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No. 93-2052

In The

Supreme Court of the United States

October Term, 1994

CONNIE ALBRECHT, ET AL.,

Petitioners,

v.

UNITED STATES DISTRICT COURT JUDGE FOR THE NORTHERN DISTRICT OF ALABAMA HONORABLE SAM C. POINTER, JR., PRESIDING AND McGHAN MEDICAL CORPORATION, ET AL.,

Respondents.

Petition For Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

BRIEF OF RESPONDENT DOW CORNING CORPORATION IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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CORPORATE DISCLOSURE STATEMENT

The following corporations are affiliated with Respondent Dow Corning Corporation and are disclosed in accordance with United States Supreme Court Rule 29.1: The Dow Chemical Company; Corning Incorporated; Dow Corning Krafft S.A.; Dow Corning STI S.A.; Devonshire Underwriters Ltd.; Dow Corning S.A.; Dow Corning Toray Silicone; Dow Corning de Mexico S.A. de C.V.; Dow Corning Limited; Dow Corning Singapore Pte. Ltd.; Dow Corning de Venezuela S.A.; Dow Corning Malaysia Sdn. Bhd.; Dow Corning Chile S.A.; Dow Corning (Thailand) Limited; Dow Corning STI Limited; Dow Corning Taiwan Inc.; Dow Corning Construction S.A.; Dow Corning Do Brasil Limitada; Dow Corning Foreign Sales Corporation; Dow Corning Investment S.A.; Dow Corning Argentina S.A.; Dow Corning Coordination Center S.A.; Dow Corning Hansil, Ltd.; Dow Corning France, S.A.; Dow Corning de Columbia S.A.; Hemlock Semiconductor Corporation; Lucky-DC Silicone Co., Ltd.; SDC Coatings Inc.; Siltech Limited; and Universal Silicones and Lubricants Private Ltd.

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COUNTER-STATEMENT OF THE CASE

This case is one of many filed in the state and federal courts by silicone breast implant recipients. Beginning in June 1992, the federal breast implant cases were transferred pursuant to 28 U.S.C. §1407 to the Northern District of Alabama, Southern Division, and consolidated for pretrial proceedings before District Judge Sam C. Pointer, Jr. *See In re: Silicone Gel Breast Implant Products Liability Litigation, No. 926*, 793 F.Supp. 1098 (Jud. Pan. Mult. Lit. 1992).

Since that time, Judge Pointer has taken an active role in all phases of the litigation. He issued two exhaustive case management orders which included orders appointing National Liaison Co-Counsel for Plaintiffs. Res.App. at pp. A-65 and A-69.[1] Among the duties of such liaison counsel was to accept service of all orders, motions, briefs and other documents which would otherwise have had to be served on the many individual Plaintiffs' counsel.[2]

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[1] Respondent will cite to Petitioners' Appendix as well as to its own. Respondent's Appendix begins with page A-65.

[2] Likewise, Judge Pointer appointed a Plaintiffs' National Steering Committee to coordinate discovery and other pre-trial proceedings on behalf of Plaintiffs. Judge Pointer has directed the conduct of consolidated and comprehensive discovery, overseen the maintenance of a joint federal-state document depository and ordered and approved the drafting of master pleadings tailored to this litigation. He has held monthly status conferences to monitor the progress of the litigation, to resolve disputes and to allow parties in attendance to be heard on many issues. As a general rule, Judge Pointer has varied the location of the status conferences to accommodate parties and counsel in other parts of the country. Moreover, it has been his practice at each conference to announce the date of the next conference in open court.

Judge Pointer has also encouraged and assisted the parties in the negotiation of a global settlement of all claims related to silicone breast implants. On April 1, 1994, a non-mandatory settlement class was conditionally certified by Judge Pointer in *Lindsey, et al. v. Dow Corning Corp., et al.*, Civil Action No. CV94-P-11558-S (N.D. AL) Res.App. at p. A-84. The *Lindsey* class includes, among others, all persons who were implanted before June 1, 1993, with silicone breast implants, whether or not they have been removed or may later be removed, with respect to any existing or future claims. A fairness hearing is scheduled to take place on August 18, 1994 to determine whether to grant final approval to the proposed Settlement Agreement as fair, adequate, and reasonable, to confirm or modify certification of the Settlement Class and to issue a Final Order and Judgment thereon. Thirty days after an order confirming and permanently certifying a class in the *Lindsey* action has become final, proposed class certification in any other federal action then pending shall be deemed as denied and class certification in the previously conditionally certified class action captioned *Dante, et al. v. Dow Corning Corp., et al.*, CV92-P-10060-S (N.D. AL)[3] shall be deemed vacated.

Petitioners filed their class action complaint in the United States District Court for the District of Utah in October 1992 and served it on Respondent Dow Corning

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[3] *Dante* was conditionally certified by Judge Carl B. Rubin in the U.S. District Court for the Southern District of Ohio, and was transferred, along with all other federal breast implant cases, to the Northern District of Alabama.

Corporation by summons dated October 29, 1992. By the time the process was received by Respondent, Petitioners had filed a motion for class certification in Utah district court. Res.App. at p. A-99. However, on October 30, 1992, while the action was still pending in Utah, Petitioners' counsel wrote to the district court in Alabama asking that it set the class certification motion for hearing in December 1992 or early January 1993. Pet.App. at p. A-15. The lawsuit had not yet been transferred to the multidistrict litigation proceedings and Judge Pointer as yet had no jurisdiction over the case.

The underlying suit appeared on Conditional Transfer Order No. 9, dated November 24, 1992. On or about December 8, 1992, the transfer of the case (and as a practical matter, the case file) from the District of Utah was effected and the district court in Alabama assumed jurisdiction over the case for all purposes, including decision on Petitioners' pending motion for class certification.

Petitioners' October 30, 1992 letter did not request an *evidentiary* hearing, nor did Petitioners make a proffer of the evidence, if any, which they intended to offer in support of their motion for class certification. Likewise, the motion itself offered no documentary evidence, by affidavit or otherwise, in support of class certification nor did it intimate any plan to supply evidence thereafter by any means. The motion also failed to provide any facts peculiar to the class members which would have provided the district court with new or different information on silicone breast implants or the women in whom they have been implanted. In fact, Petitioners' memorandum in support of their motion stated:

> Although asserting three distinctive legal theories, the factual background of this newly filed case is substantially similar with or identical to all other cases which have been consolidated to the Federal District Court in Birminghan, Alabama pursuant to MDL Order No. 926. Res.App. at pp. A-101-102.

On January 2, 1993, the district court, in a regularly scheduled status conference, denied Petitioners' motion. District Judge Pointer stated:

> To the extent that these are appropriate claims and to the extent we're going to have a class, I can deal with it in other litigation without the need to utilize this particular device for certain limited theories of action. That is in no way a ruling on the merits of whether any such claims could be presented individually or as a class theory. Pet.App. at pp. A-13-14.

Petitioners' counsel did not attend this status conference.[4] In an April 29, 1993 letter, Petitioners' counsel again requested that the district court decide the motion for class certification. Pet.App. at p. A-17. Once again, Petitioners did *not* 1) request an *evidentiary* hearing, 2) offer any evidence or, 3) articulate additional facts to the court. They did, however, reiterate many of the arguments which they had made in their written motion.

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[4] It is common practice in MDL-926 for counsel to notify the district court of pending motions and appear at subsequent hearings for argument and ruling. Any questions by the parties regarding MDL-926 practice and procedure are and should be addressed to the respective liaison counsel.

After being notified (by Respondent) that the district court had denied the class certification motion, Petitioners again wrote to the court. Res.App. at p. A-118. Petitioners' counsel advised the court of arguments which he would have made, had he been present at the status conference. Again, he gave no indication of additional facts or evidence which he sought to bring to the court, or which would warrant an evidentiary hearing. The district court issued a written order on May 25, 1993 again denying class certification. Pet.App. at p. A-11.

On or about June 22, 1993, Petitioners filed a motion citing Rule 52, Fed. R. Civ. P., requesting the district court to enter Findings of Fact and Conclusions of Law in support of the order denying class certification. The district court granted Petitioners' motion, entering the following observation:

> The court CONCLUDES that to the extent that a class action will be utilized, the claims stated by the plaintiff on behalf of all women without bodily injuries can be dealt with most efficiently in other existing litigation rather than through a separate class action for these limited causes of action. Pet. App. at p. A-10.

On or about February 11, 1994, Petitioners filed a Petition for a Writ of Mandamus in the Court of Appeals for the Eleventh Circuit. Petitioners sought the writ 1) to compel Judge Pointer to vacate his order denying class certification, 2) to direct him to hold an evidentiary hearing on Petitioners' motion for class certification and 3) to require him to make appropriate findings of fact after the hearing. Pet.App. at p. A-28. This was the first mention of an *evidentiary* hearing, but Petitioners again made no

specific proffer or general description of the evidence which they would present at such a hearing. On or about March 11, 1994, the Eleventh Circuit denied the petition. Pet.App. at p. A-1.

Thereafter, this Petition was filed addressed to the class certification process and the role of the Nuremberg Code in U.S. law.

SUMMARY OF REASONS FOR DENYING THE WRIT

Petitioners attack the district court's order denying certification of a class arguing that the district court failed to "appreciate" the Nuremberg Code as the basic ethical standard for human experimentation. Pet. at p. 9. They ask this Court to find the Nuremberg Code to be part of due process constitutional law or federal common law. This issue may not be decided by the Supreme Court because the sufficiency of Petitioners' Nuremberg Code cause of action was not adjudicated in the lower courts. Therefore, the issue is not ripe for *certiorari*.

Petitioners also assail the court of appeals' refusal to issue a writ of mandamus vacating the district court's order of denial of class certification. This Court has clearly stated that a writ of mandamus is proper only in the extraordinary circumstance in which it is clear and indisputable that an abuse of discretion rising to the level of judicial usurpation of power has occurred and must be remedied. Petitioners have failed to assert that such an abuse took place in this case and furthermore, they have

failed to explain how a favorable resolution of the questions which they have broached to this Court would ultimately change the outcome in the district court.

REASONS FOR DENYING THE WRIT

I. THE LOWER COURTS HAVE NOT REACHED OR ADJUDICATED THE SUFFICIENCY OF PETITIONERS' CAUSE OF ACTION BASED ON THE NUREMBERG CODE

Petitioners sought to certify a plaintiff class to press a claim based on the Nuremberg Code which Petitioners characterize as a "common law ethical standard for human experimentation." Pet. at p. 3. They ask this Court to find that the Nuremberg Code is part of "due process constitutional law or federal common law." Pet. at p. 3. There is no legal authority whatsoever for the proposition that the Nuremberg Code creates a cause of action or, as asserted by Petitioners, has "been considered to be common law" by courts. Pet. at p. 13, n.11.[5] There has been no

[5] Petitioners cite *Strunk v. Strunk*, 445 S.W.2d 145 (Ky. App. 1969) as a case in which the Nuremberg Code was found to be a part of the common law. This case does not even deal with human experimentation, but rather with the issue whether a court of equity has the power to allow a kidney to be removed from an incompetent donor for transplant into his severely ill brother. The *Strunk* court *does not even mention* the Nuremberg Code. Likewise, Petitioners' reliance on *Pierce v. Ortho Pharmaceutical Corp.*, 84 N.J. 58, 417 A.2d 505 (1980) is misplaced. That case asked whether a physician-researcher employee had a cause of action for wrongful discharge where she perceived that

ruling at any stage, in any court, pro or con, on this point in this action or the underlying action.

In Count XIII of their Complaint and the Amendments thereto, Petitioners pleaded the purported elements of a claim based on the Nuremberg Code. They sought class certification against Respondent Dow Corning Corporation, only.

The district court denied class certification, without ruling on the Nuremberg Code claim. Its Findings of Fact, dated July 12, 1993, held that the claims by Petitioners on behalf of all women "without bodily injuries" could be dealt with more efficiently in preexisting litigation rather than through a new separate class action for the Nuremberg Code claims. Pet.App. at p. A-10. The court cautioned that its denial of class certification was, in no way, a ruling on the merits or sufficiency of the Nuremberg Code claim, either for any plaintiff class or individual. Pet.App. at p. A-14. Consequently, Petitioners' assertion that the district court "ignored" the Nuremberg Code is

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her research activities would cause her to violate ethics expressed in the Hippocratic Oath. Only the dissent raises the Nuremberg Code as "clear mandate of public policy." *Id.* at 516-17.

The courts in *Kamowitz v. Michigan Department of Mental Health*, Civ. No. 73-19434-AW (Mich Cir. Ct. 1973), and *Whitlock v. Duke University*, 637 F.Supp.1463 (M.D.N.C. 1986) simply looked to the Nuremberg Code for guidance in the absence of statutory or other authority on informed consent in the context of human experimentation. Neither court adopted the Code as binding precedent to govern cases of experimentation with human subjects, let alone a product liability claim against a non-physician.

false. Denial of class certification by the district court was not a ruling on the substantive merits of any claim.

Neither did the court of appeals adjudicate Petitioners' Nuremberg Code claims. Petitioners' mandamus petition was addressed solely to the process by which the district court denied class certification, and did not reach the merits of the case. Even Petitioners did not ask the court of appeals to recognize a federal cause of action based on the Nuremberg Code because it was clear that the district court had not yet refused to do so. Therefore, there is no decision by any court below, presented here for review by the Supreme Court, on the sufficiency of this novel and imaginative theory. In fact, it is not even possible for this Court to render a decision on Petitioners' Nuremberg Code question as the issue has not been litigated by the parties, or disposed of by any court at the trial level.

To date, Petitioners' Nuremberg Code claims remain pending. Each petitioner who does not choose to participate in the "global" settlement described *supra* is free to pursue her Nuremberg Code claim individually against Respondent Dow Corning Corporation. At that time, the viability of a cause of action based on the Nuremberg Code may well be challenged by Respondent. At the very least, unless and until the district court first rules (adversely or favorably to Petitioners) on this issue and the court of appeals has had opportunity to review that ruling, it is not ripe for *certiorari*. Obviously, the issue may never become ripe in this case. Thus, the Petition should be denied.

II. A WRIT OF MANDAMUS TO A DISTRICT COURT JUDGE IS PROPER ONLY WHERE IT IS CLEARLY AND INDISPUTABLY SHOWN THAT AN ABUSE OF DISCRETION CONSTITUTING JUDICIAL USURPATION OF POWER MUST BE REMEDIED.

This Court has described mandamus against a United States district judge as a drastic remedy. *Kerr v. United States District Court for the Northern District of California*, 426 U.S. 394, 402 (1976). Its use is to be reserved for the exceptional circumstance constituting "judicial usurpation of power." *Will v. United States*, 389 U.S. 90, 95 (1967). The seminal case cited in *Will* also cautions that "mere error in the exercise of conceded judicial power" is not enough. *DeBeers Consol. Mines v. United States*, 325 U.S. 212, 217 (1944). *At best*, Petitioners' petition for mandamus stated an allegation of a single isolated instance of "mere error" in the denial of class certification. The writ was properly denied.

A. Petitioners do not allege a clear and indisputable right to issuance of the writ.

Due to the coercive nature of any writ of mandamus issued against a federal district judge, a party seeking the writ must satisfy a very high standard of proof. The right to mandamus must be clear and indisputable. *Mallard v. United States District Court for the Southern District of Iowa*, 490 U.S. 296, 309 (1989), quoting *Bankers Life and Casualty Co. v. Holland*, 346 U.S. 379, 384 (1953), quoting *United States v. Duell*, 172 U.S. 576, 582 (1899). Further, this Court has recognized that the issuance of mandamus is within

the discretion of the court being petitioned for the writ. *Kerr v. United States District Court*, 426 U.S. at 403.

Thus, a party seeking review of the denial of mandamus must, at the least, allege an abuse of discretion and the disregard of a clear and indisputable right to the writ. However, Petitioners allege no abuse of discretion by the court of appeals, rather phrasing their arguments as if they were appealing from the district court's order in the underlying suit. Petitioners also fail to allege a clear and indisputable right to the writ or that the same was shown to the court of appeals. Instead, Petitioners ask this Court to resolve several issues of law relating to a highly discretionary device (mandamus) without explaining how resolving those issues could ultimately change the outcome on remand.

B. This case presents no controversy on the right of circuit courts of appeals to issue mandamus on class certification issues.

Petitioners' claim that this case "presents . . . an opportunity to establish uniform criteria for mandamus review," Pet. at p. 22, is simply inaccurate. Nothing suggests that the court of appeals doubted its authority – in a proper case – to issue mandamus concerning class certification. Petitioner concedes that the Eleventh Circuit recognizes its authority in this regard. *See In re Temple*, 851 F.2d 1269 (11th Cir. 1988), cited at page 24 in the Petition. Petitioners, in positing a conflict among the circuits on whether mandamus is available on class certification issues, erect a straw man. No party before this

Court in this case will argue that such authority is lacking. Respondents' position on class certification has already been sustained without the necessity that they even take a position on whether the circuit court had authority to issue mandamus. Neither the district court nor this Respondent will gratuitously assault the precedent of the Eleventh Circuit on an issue on which *Respondents have already prevailed.*

This is not a case in which the availability of mandamus is an active controversy. Even if it were, Petitioners have neither shown nor even alleged how any standard which they will urge this Court to adopt will procure the writ for them on remand. Likewise, Petitioners never argued for any change in the law of mandamus in the Eleventh Circuit, and therefore should not be permitted to do so here.

C. Petitioners have shown no reason why this court should involve itself in multidistrict litigation in an area within the district court's discretion.

Mandamus actions against district judges make judges unwilling participants in litigation and may leave their defense in the hands of parties to the underlying litigation. *Ex Parte Fahey,* 332 U.S. 258, 260 (1947). The potential for misuse of a mandamus action to obtain an otherwise unavailable interlocutory appeal has also been recognized. *Bankers Life & Cas. Co. v. Holland,* 346 U.S. 379, 382-83 (1953).

Mandamus actions against federal judges have been limited to circumstances in which a judge has committed

a degree of abuse of discretion which exceeds "ordinary" abuse. *In re Catawba Indian Tribe*, 973 F.2d 1133, 1137 (4th Cir. 1992). This "high abuse" has long been characterized as "judicial usurpation of power." *See Will v. United States*, 389 U.S. 90, 95 (1967). Where a ruling of law is made in the course of a judge's jurisdiction on an issue properly before the judge, that ruling, even if erroneous, is not an abuse of power warranting mandamus. *See Bankers Life* at 382-83. Similarly, denial of class certification in this case constituted no abuse of power.

Petitioners claim that no "hearing" was held and no "meaningful" findings of fact and conclusions of law were issued by Judge Pointer.[6] The motion for class certification was discussed at a regularly scheduled MDL-926 status conference which Petitioners' counsel did not attend. This was a "hearing" in keeping with normal practice in this MDL proceeding. The class certification question was decided on the basis of the Petitioners' memorandum, and reconsidered in response to Petitioners' written protests. Only in the court of appeals was an "evidentiary hearing" demanded. Never, to this day, have Petitioners hinted what evidence they planned to offer on a motion on which they had, so far, offered none. Ultimately, a written order was issued stating the court's conclusions in light of Petitioners' arguments for reconsideration.

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[6] Rule 52(a) Fed.R.Civ.P., by its terms, makes findings of fact and conclusions of law "unnecessary" for a ruling on a class certification motion. The rule obviates what Petitioners maintain it requires.

The entire objective of multi-district litigation is the efficiency associated with having the cases managed by a single judge familiar with all aspects of a complex litigation. The Petitioners may properly seek review only of the judgment of the court of appeals, and not of the interlocutory order of Judge Pointer, which is not, and has not yet become, appealable.

CONCLUSION

For the foregoing reasons, the Petition should be denied.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re:	)	Master File
	)	No. CV 92-P-10000-S
SILICONE GEL BREAST IMPLANTS PRODUCTS LIABILITY LITIGATION (MDL-926)	)	This Document Relates to: All Cases

ORDER NO. 1
(Initial Case Management Order)

(Filed June 26, 1992)

It appearing that the cases listed on Attachment A, which have been transferred to this court under 28 U.S.C. § 1407, merit special attention as complex litigation, the court ORDERS:

1. **Initial Conference.** The court will conduct a conference under Fed. R. Civ. P. 16 and 26(f) at 9:00 a.m., Monday, July 20, 1992, in Courtroom 8 at the Hugo L. Black Courthouse, Birmingham, Alabama.

(a) **Attendance.** To minimize costs and facilitate a manageable conference, parties are not required to attend the conference, and parties with similar interests are expected to agree to the extent practicable on a single attorney to act on their joint behalf at the conference. A party will not, by designating an attorney to represent its interests at the conference, be precluded from other representation during the litigation; and attendance at the conference will not waive objections to jurisdiction, venue, or service.

(1) **Service List.** This order is being mailed to the persons shown on Attachment B, which has been prepared from the list of counsel making appearances with the Judicial Panel on Multidistrict Litigation. Counsel on this list are requested to forward a copy of the order to other attorneys who should be notified of the conference. A corrected service list will be prepared after the conference.

(2) **Other Participants.** Counsel for persons or entities who are not named as parties in the cases initially transferred by the JPMDL but may be later joined as parties or are parties in related litigation pending in other federal and state courts are welcome to attend the conference.

(b) **Purposes; Agenda.** The conference will be held for the purposes specified in Fed. R. Civ. P. 16(a), 16(b), 16(c) and 26(f). A tentative agenda is appended as Attachment C.

(c) **Preparations for Conference.**

(1) **Procedures for Complex Litigation.** Counsel will familiarize themselves with the *Manual for Complex Litigation, Second,* and be prepared at the conference to suggest procedures that will facilitate the expeditious, economical, and just resolution of this litigation.

(2) **Meeting of Counsel.** Before the conference, counsel for the plaintiffs and counsel for the defendants shall separately confer and seek consensus to the extent possible with respect to the items on the agenda, including a proposed discovery

plan under Rule 26(f), methods to obtain discovery of expert testimony, and the timing for consideration of motions and for resolution of controversies regarding maintenance of one or more cases as class actions.

(d) **Preliminary Reports.** Counsel will submit to the undersigned by July 14, 1992, a *brief* written report indicating their preliminary understanding of the facts involved in the litigation and what they expect to be the critical factual and legal issues. These statements will not be filed with the Clerk, will not be binding, will not waive other claims or defenses, and may not be offered in evidence against a party in later proceedings. To the extent feasible, the statements of parties with similar interests should be consolidated and submitted as a single document.

(1) **List of Affiliated Companies and Counsel.** To assist the court and other counsel in identifying any problems of recusal or disqualification, the reports should include as an appendix a list of all companies affiliated with the parties and of all counsel associated in the litigation.

(2) **List of Pending Motions.** The reports should briefly summarize the nature of pending motions.

(3) **State Court Litigation.** The reports should briefly summarize, to the extent known, the nature and status of similar litigation pending in state courts.

(4) **Lead and Liaison Counsel; Steering Committee.** Attorneys interested in

serving as Lead, Liaison, or Coordinating Counsel or on a committee of counsel to assist in coordination and management of the litigation shall also submit information outlining how and at what rates they will expect to be compensated or reimbursed for services rendered to other parties and counsel and what agreements or commitments they have made respecting the role and responsibility of other attorneys in conducting pretrial proceedings, discovery, and trial.

2. **Interim Measures.** Until otherwise ordered by the court:

(a) **Admission of Counsel.** Attorneys admitted to practice and in good standing in any United States District Court are hereby permitted to appear pro hac [sic] vice in this litigation, without need for any other motion, order, or payment of fee. Association of local counsel is not required.

(b) **Pretrial consolidation.** The cases listed on Attachment A are consolidated for pretrial proceedings. This order does not constitute a determination that these actions should be consolidated for trial, nor does it have the effect of making any entity a party to an action in which it has not been joined and served in accordance with the Federal Rules of Civil Procedure.

(1) **Master Docket and File.** The Clerk will maintain a master docket and case file under the style "In re Silicone Gel Breast Implants Product Litigation (MDL-926)" as master file number CV 92-P-10000-S. All

orders, pleadings, motions, and other documents will, when filed and docketed in the master case file, be deemed filed and docketed in each individual case to the extent applicable.

(2) **Captions; Separate Filing.** Orders, pleadings, motions and other documents will bear a caption similar to that of this order. If generally applicable to all consolidated actions, they shall include in the caption the notation that they relate to "All Cases" and shall be filed and docketed only in the master file. Documents intended to apply only to particular cases will indicate in their caption the case number of the case(s) to which they apply, and extra copies shall be provided to the Clerk to facilitate filing and docketing both in the master case file and in the specified individual case files.

(c) **Pleadings.** Each defendant is granted an extension of time for responding by motion or answer to the complaints until a date to be set at the conference.

(d) **Motions.**

(1) No motion shall be filed under Rule 11 or Rule 56 without leave of court.

(2) No motion (other than under Rule 12) shall be filed unless it includes a certification that the movant has conferred with opposing parties and made a good faith effort to resolve the matter without court action.

(3) **Preservation of Records.** Each party shall preserve all documents and

other records containing information potentially relevant to the subject matter of this litigation. Subject to further order of the court, parties may continue routine erasures of computerized data pursuant to existing programs, but they shall (1) immediately notify opposing counsel about such programs and (2) preserve any printouts of such data. Requests for relief from this directive will receive prompt attention from the court.

(f) **Discovery.**

(1) **Non-filing of Discovery Documents.** Pursuant to Fed. R. Civ. P. 5(d), discovery requests and responses will not be filed with the court except when specifically so ordered by the court or to the extent needed in connection with a motion.

(2) **Pending and New Discovery.** Pending the conference, all outstanding discovery proceedings are stayed and no further discovery shall be initiated. This directive does not (A) preclude informal discovery regarding the identification and location of relevant documents and witnesses; (B) preclude parties from stipulating to the conduct of a deposition that has already been scheduled; (C) prevent a party from voluntarily responding to an outstanding discovery request under Rule 33, 34, or 36; or (D) authorize a party to suspend its efforts in gathering information needed to respond to a request under Rule 33, 34, or 36. Relief from this stay may be granted for good cause shown, such as the ill health of a proposed deponent.

(3) **Deadlines.** Orders issued by transferor courts imposing dates for initiation or completion of discovery are vacated.

(g) **Magistrate Judge.** The undersigned expects to handle personally, to the extent practical, all matters requiring or deserving judicial attention, including discovery disputes. In the absence or unavailability of the undersigned, matters requiring immediate judicial attention are automatically referred, without need for special order, to Magistrate Judge Elizabeth Todd Campbell for disposition or report and recommendation as may be appropriate.

(h) **Later Cases.** The interim orders contained in this paragraph 2, including pretrial consolidation, shall apply automatically to actions later instituted in, removed to, or transferred to this court (including cases transferred for pretrial purposes under 28 U.S.C. § 1407) that involve claims relating to silicone gel breast implants.

This the 26th day of June, 1992.

/s/ Sam C. Pointer, Jr.
United States District Judge

Attachments:
A– List of cases
B – Service list
C – Tentative agenda

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re:	)	Master File No.
	)	CV 92-P-10000-S
SILICONE GEL BREAST IMPLANTS PRODUCTS LIABILITY LITIGATION (MDL-926)	)	(This Document Relates To: All Cases)

Order No. 5
(Revised Case Management Order)

(Filed Sept. 15, 1992)

On July 20-21, 1992, and August 21, 1992, conferences were held pursuant to Rule 16 in Birmingham, Alabama. This order is entered as a result of discussions at those conferences. It supplements and, to the extent inconsistent, supersedes all prior orders and applies to all cases that have been or are subsequently filed in, removed to, or transferred to this court as part of the Silicone Gel Breast Implant Litigation, including any cases involving other implant product liability claims considered suitable for inclusion in this litigation. A copy of Exhibit A to this Order will be filed and docketed in each such case.

Caution: The terms of this order automatically apply to cases transferred to the Northern District of Alabama under 28 U.S.C. § 1407 once the transfer order from the JPMDL has been filed in this court. Until that time (including the time a conditional transfer order is pending), the terms of this order do not apply to a case filed in another district unless that court so orders.

1. **Admission of Counsel.** Attorneys admitted to practice and in good standing in any United States District Court are hereby permitted to appear pro hac [sic] vice in this litigation without need for any other motion, order, or payment of fee. Association of local counsel is not required.

2. **Pretrial Consolidation.** All cases in this litigation are consolidated for pretrial purposes. This is not a determination that any of these actions should be consolidated for trial, and does not have the effect of making any entity a party to an action in which it has not been named and served.

3. **Filing of Papers with Court.** The purpose of the following instructions is to reduce the time and expense of duplicate filings of documents through use of a master case file, while at the same time not congesting the master case with miscellaneous pleadings and orders that are of interest only to the parties directly affected by them. It is not intended that a party would lose any rights based on a failure to follow these instructions.

(a) **Master Docket and File.** The Clerk will maintain a master docket and case file under the style "In re Silicone Gel Breast Implants Product Litigation (MDL-926)" as master file number CV 92-P-10000-S. Orders, pleadings, motions, and other documents bearing a caption similar to that of this order will, when docketed and filed in the master case, be deemed as docketed and filed in each individual case to the extent applicable and will not ordinarily be separately docketed or physically filed in such individual cases.

However, the caption may also contain a notation indicating whether the document relates to all cases or only to specified cases.

(b) **Separate Filing.** A document that relates only to a specific case and would not be of interest except to the parties directly affected by it – such as an amended complaint adding a party or a motion to dismiss a party – should bear the caption and case number of that case rather than of the master case file. Such a document will be docketed and filed in that case and not in the master case file. Please note that cases removed or transferred to this court are assigned a new case number in this court.

(c) **Address; Number of Copies.** When filing documents with the court, send only one signed original to the Clerk, U.S. District Court, Federal Courthouse, Birmingham, AL 35203. Documents should be stapled once and should not have "blue backs" or other cover sheets. Unless specifically requested by the court, do not submit additional copies to the Clerk or send informational copies to the judge's chambers.

(1) **Telephone Numbers.** The telephone number for the Docket Clerk handling these cases is (205)731-2038. Access to PACER (a computerized service for obtaining docket information) is (205)731-3502. The general telephone number for the Clerk's office is (205)731-1701.

(2) **FAX.** Litigants may transmit documents to the Clerk by FAX only if advance approval is given by the undersigned. This approval should be requested only in exigent circumstances where transmission by

other methods is not feasible. The Clerk's FAX number is (205)731-0742.

(d) **Briefs; Correspondence.** Send to the judge's chambers (Room 882, Federal Courthouse, Birmingham, Alabama, 35203) any briefs, correspondence, and other similar materials that are not due to be docketed. Send only one copy. Do not send a copy of such materials to the Clerk.

(1) **Telephone Number.** The telephone number for the judge's chambers is (205)731-1709.

(2) **FAX.** Litigants may transmit documents to the judge's chambers by FAX only if advance approval is given by the undersigned. This approval should be requested only in exigent circumstances where transmission by other methods is not feasible. The chamber's FAX number is (205)731-2243.

(e) **Discovery Documents.** Pursuant to Rule 5(d), discovery requests and responses are not to be filed with the Clerk or sent to the judge's chambers except when specifically so ordered by the court or to the extent needed in connection with a motion.

(f) **Computer Files.** Counsel using computers to prepare documents sent to the Clerk or to the judge's chambers are asked to retain computer-readable text files of these documents. The court contemplates that procedures will be established for maintaining an electronic library of these files for quick and inexpensive access by other litigants and interested parties.

4. **Service of Original Complaints; Amendment Adding Parties.**

(a) **Acceptable Service.** Exhibit B is a list of the "National Defendants" – that is, those entities that have frequently been named as defendants in these cases filed throughout the United States – showing also their national counsel and (according to their counsel) the state(s) in which they are incorporated, in which they have their principal place of doing business, and in which they will or may contest personal jurisdiction. To eliminate disputes over service of process and reduce the expense of such service, these defendants have agreed to accept service of process in these cases (without, however, waiving any objections to personal jurisdiction or venue) if a copy of the summons and complaint is sent by certified mail, return receipt requested, to the person or address shown in the Fifth Column of Exhibit B. This agreement applies to any case involving silicone gel product liability claims filed in any federal district court or in any state court of general jurisdiction.

(b) **Extension of Time to Serve.** Notwithstanding the provisions of Rule 4(j), plaintiffs shall have thirty days after the date of this order (or, if later, thirty days after the date a case is subsequently filed in, removed to, or transferred to this court) in which to effect service on defendants.

(c) **Leave to Add Parties.** Until otherwise directed, plaintiffs are granted leave, without need for any special motion or order, to add other plaintiffs to any pending (or subsequently

filed, removed, or transferred) case if all plaintiffs in the case (1) will be represented by the same counsel (or if counsel for existing plaintiffs consent to the intervention), (2) all plaintiffs are suing the same defendants, and (3) all plaintiffs had their implant(s) performed in the same state. The purpose of this authorization is to avoid unnecessary filing fees and the delays inherent in 28 U.S.C. § 1407 transfers. The joinder of such parties will not be viewed as affecting subsequent motions by either plaintiffs or defendants for separate trials under Rule 42(b). Plaintiffs choosing to add parties under this authorization are, to the extent claims are made against any of the "National Defendants" listed in Exhibit B, requested to send a copy of the amended complaint to such agent or address in addition to serving liaison counsel as specified in paragraph 5(a).

5. **Service of Other Documents.**

(a) **National Liaison Counsel.** Service of all orders, pleadings (other than the original summons and complaint), motions, briefs, and other documents will be effective on all parties when made on the following persons who, as provided in Order No. 2, have been designated as National Liaison Counsel:

(1) National Liaison Co-Counsel for Plaintiffs:

Mr. Francis H. Hare, Jr.
Hare, Wynn, Newell & Newton
Suite 800, Massey Building
290 North 21st Street
Birmingham, AL 35203
Telephone: (205)328-5330
FAX: (205)323-8276 or 324-2165

Mr. J. Michael Rediker
Ritchie & Rediker
312 North 23rd Street
Birmingham, AL 35203
Telephone: (205)251-1288
FAX: (205)324-7830

(2) National Liaison Counsel for Defendants:

Mr. Frank C. Woodside, III
Dinsmore & Shohl
1900 Chemed Center
255 East Fifth Street
Cincinnati, OH 45202
Telephone: (513)977-8266
FAX: (513)977-8141

Documents received by liaison counsel by 11:59 p.m. on Thursday of any week are considered served as of 4:00 p.m. on Friday of that week. Liaison counsel are responsible for promptly distributing copies to the parties for whom they are acting as liaison counsel on a "need to know" basis and for providing a convenient, inexpensive means by which any other parties for whom they are acting can obtain copies if desired.

(b) Additional Service.

(1) **Defaults; Sanctions.** Motions claiming default or seeking other penalties or sanctions against a party for failure to take some action within a time period measured from the date of service of a document must also be served on counsel of

record for that party (or, if the party is listed in Exhibit B, on the national counsel for that party).

(2) **Informational Copies.** If a document affects only a particular party or a particular case – for example, a motion seeking to dismiss a party in a case or to remand a case to state court – service of an additional copy upon counsel of record for that party or in that case (or, for those defendants listed on Exhibit B, their national counsel for this litigation) is encouraged, but not required.

(c) **Computer Files.** Counsel using computers to generate documents served on other parties are asked to retain computer-readable text files of these documents. It is contemplated that procedures will be established for maintaining a library of such materials for quick and inexpensive access by other litigants and interested parties.

6. **Master Pleadings; Motions; Orders.**

(a) **Master/Sample Complaints.** Plaintiffs' National Steering Committee has filed in CV 92-P-10000-S (1) a master complaint containing allegations that would be suitable for adoption by reference in individual cases and (2) a sample complaint illustrating how allegations from the master complaint can be incorporated into an individual case.

The allegations of the master complaint are not deemed automatically included in any particular case. However, in order to avoid possible problems with statutes of limitations or doctrines of repose, it shall be

deemed (except to the extent a plaintiff thereafter files an amended complaint disavowing such claims and theories or limits its claims and theories to those contained in an amended complaint) that as of this date, for cases now pending in this court (or as of the date other cases are filed in, removed to, or transferred to this court) a motion is filed in each such case to amend the complaint to add any potentially applicable claims and theories from the master complaint not contained in the complaint actually filed in that case.

(b) **Master Answers.** By October 15, 1992, each entity listed in Exhibit B will file in CV 92-P-10000-S a master answer that incorporates its defenses in law or fact to claims made against it in the various actions that are presently pending in this litigation, including any cross-claims it makes against other defendants. The answer will not attempt to provide a cross-reference to particular paragraphs or counts of the various complaints. The answer will, however, in a "generic" manner admit or deny (including denials based on lack of information and belief) the allegations typically included in claims or cross-claims made against it as well as make such additional allegations as are appropriate to its defenses or cross-claims. This may be done through allegations such as "It alleges . . . that it is incorporated in State A; that it has its principal place of business in State B; that during the period from (date) to (date) it manufactured, sold, and distributed products intended to be used in breast implant procedures; that these products were intended to be used only by trained, knowledgeable physicians and were

accompanied by warnings and instructions that adequately explained such risks as were inherent and unavoidable in the products; that these products were not unreasonably dangerous, were suitable for the purposes for which they were intended, and were distributed with adequate and sufficient warnings; that it is without knowledge or information at this time sufficient to form a belief as to any averment that one of its products was used in the implant procedure on which the plaintiff's complaint is based; that to the extent the plaintiff makes a claim for X (or under Statute Y) it is not liable because . . . ; etc."

(1) When so filed in CV 92-P-10000-S, these answers constitute an answer in each constituent case now pending or when hereafter filed in, removed to, or transferred to this court except to the extent the defendant later files a separate answer in an individual case.

(2) A defendant not listed in Exhibit B *may* also file a master answer in CV 92-P-10000-S by October 15, 1992, or within 45 days after the first case in which it is named as a defendant is filed in, removed to, or transferred to this court.

(c) **Refinement of Pleadings.** It is anticipated that an amended, more specific complaint and answer may be required before a case is scheduled for trial or remanded to a transferor court, but that amendments of pleadings prior to that time should generally be avoided.

(d) **Motions; Orders.** A motion, brief, or response that has potential effect on multiple parties (e.g., documents submitted in connection

with a motion for partial summary judgment asserting that punitive damages are not recoverable with respect to implants performed in State A) will be deemed made in all similar cases on behalf of, and against, all parties similarly situated except to the extent such other parties timely disavow such a position. Additional motions, briefs, or responses addressed to such issues should not be filed or submitted by other parties except to the extent needed because of inadequacy of the original papers, to present unique facts, or a difference in positions. Order resolving such motions will likewise be deemed as made with respect to all parties similarly situated unless the order indicates otherwise.

(e) **Motions under Rule 11 and Rule 56.** No motion shall be filed under Rule 11 or Rule 56 without leave of court.

(f) **Effort to Resolve Without Court Intervention.** Any motion relating to discovery or any other subject on which accord of affected parties might reasonably be expected shall contain a certificate that the movant has conferred with other affected parties and made a good faith effort to resolve the dispute without need for court intervention.

7. **Discovery.**

(a) **Concepts and Objectives.** The plan for document production, interrogatories, requests for admission, and depositions has been developed based on the following principles: (1) discovery should be conducted on the assumption that there may be a separate trial of each case (federal or state); (2) additional "true discovery"

will not be needed with respect to many potential witnesses who have previously testified in depositions or in trials; (3) videotaped depositions (which are also stenographically recorded) should be taken for potential use as trial testimony of all persons whose testimony will likely be needed in a number of trials, thereby enabling trials to be conducted in different courts at the same time without complications arising from unavailability of witnesses; (4) through use of a joint plaintiff-defendant federal-state library, all parties in any federal or state court should have quick and inexpensive access to, and the ability to retrieve, (A) all existing and future depositions, interrogatories, requests for admission, and trial transcripts in text-readable and searchable computer files and (B) all potentially relevant documents from the defendants and other sources that are likely to be used during depositions or at trial in more than a single case; (5) claims of confidentiality and use of "protective" orders restricting use of materials should be kept to an absolute minimum; (6) some discovery will be "national" in scope (i.e., potentially needed in various cases throughout the country), while other discovery will be "regional" (e.g., depositions from plastic surgeons performing numerous implants) and still other discovery will be "case-specific" (e.g., depositions of plaintiffs and their treating or examining physicians); (7) the plan should be designed to accommodate coordinated, cost-efficient discovery in both federal and state courts; and (8), in order to minimize unnecessary burdens and expense of redundant discovery, parties should not submit document requests, interrogatories, requests for admission,

and notices of depositions without first determining that the materials are not available in the library or are inadequate.

(b) **Plaintiffs' Steering Committee.** The court has appointed a Plaintiffs' National Steering Committee to coordinate discovery and other pretrial proceedings on behalf of the various plaintiffs. The list of these attorneys is attached as Exhibit C. The court reserves the right to change these appointments from time to time as appropriate.

(1) It is recognized that there are, and likely will continue to be, disagreements among plaintiffs with respect to various pretrial matters, particularly with respect to the planning for trial and as to whether class actions or consolidated trials may be appropriate. The designation of the Steering Committee is not intended to preclude the presentation to the court of divergent views from within the Steering Committee or by attorneys for plaintiffs who disagree with positions taken unanimously by the Steering Committee. However, counsel for individual plaintiffs should not repeat arguments, presentations, or actions of the Steering Committee.

(2) The Steering Committee may organize itself into sub-committees and may designate additional counsel to assist in performing its responsibilities.

(3) At least in states in which a substantial number of implant cases have been or may be instituted (whether in federal or state court), there will also be a state (or local) liaison counsel or steering committee,

with responsibilities for similar coordination in management of discovery that is primarily state-wide or local, such as discovery from surgeons or hospitals which have been involved in many implant and explant/removal procedures. It is expected that, if a person or committee is established by the state courts to coordinate implant litigation within that state, the same attorneys should ordinarily be designated to perform similar functions for the federal cases filed in that state.

(c) **Joint Depository.** A joint plaintiffs-defendants federal-state document depository and library will be maintained in the United States Courthouse at 100 East Fifth Street, Cincinnati, Ohio, 45202 (telephone: 513-684-6688; FAX: 513-684-5853) and supervised by Tina J. Crowe. The depository will store all materials produced by parties and third-parties that may be needed in more than single case, including documents, interrogatories, requests for admission, requests for production of documents, depositions, trial transcripts, and similar materials. These materials will be made available to litigants in any federal or state case involving implant product liability claims. It is anticipated that materials in the depository should be available from the depository for such distribution by December 1, 1992.

(1) The expenses of the depository, including the costs of imaging of documents and the compensation paid to Ms. Crowe to the extent not payable as an employee of the federal judiciary, shall be initially divided equally between the Plaintiff's National

Steering Committee and the national defendants listed in Exhibit B.

(2) Reimbursement of these expenses may be obtained by imposing user fees, but these fees will be kept to the minimum necessary to fund the costs of the depository incurred by reason of this litigation. The depository will not be conducted as a "profit-center."

(3) Plaintiffs' Steering Committee has indicated that it expects to establish additional regional electronic depositories.

(d) **Numbering.** All materials will be uniquely identified by a prefix of as many as three letters and a page number of as many as nine digits. This combination of letters and digits should then be used throughout the discovery process and at trials whenever referring to a particular document or page. All reasonable efforts should be made to avoid having the same page being assigned more than one such identifying number except when there is a need to account for different copies of the same document or page, for example because of special notations being placed on a document.

(e) Documents.

(1) Documents produced by the plaintiffs, defendants, and third-parties pursuant to Rules 33, 34, and 45 will be submitted to the depository, as will a copy of interrogatories (and responses), requests for admission (and responses), depositions, trial transcripts, and other similar materials.

(2) The "manufacturer" defendants have been directed to submit to the depository by September 15, 1992, the documents previously requested from them; and the "supplier" defendants ('21' International Holdings, General Electric, and Union Carbide) have been directed to submit to the depository by October 15, 1992, the documents requested from them.

(A) Some additional time may be needed by some defendants to produce some of the requested documents. These are to be submitted as soon as possible after the due dates.

(B) The documents to be produced include all non-privileged materials that are potentially relevant in any of the cases or that are reasonably calculated to lead to relevant evidence. After the production has been accomplished, the Plaintiffs' National Steering Committee and the particular defendant will prepare a joint statement describing the nature and scope of the documents produced that can serve as the functional equivalent of a Rule 34 request and response, enabling other litigants to understand what has been produced.

(C) Each defendant shall file by November 1, 1992, a list of any otherwise relevant documents that are not produced based on a privilege or a protection (such as for work-product materials). Documents may be withheld only

if privileged or protected against disclosure in each court (federal or state) in which they have been sued.

(D) The objective that defendants producing documents under this plan be relieved of redundant requests from plaintiffs in other federal and state cases can be accomplished only if plaintiffs can be reasonably confident that all potentially relevant documents are either produced or are specifically identified as withheld pursuant to a legitimate claim of privilege or protection against disclosure. A defendant's failure to either produce or identify as withheld a relevant document will be viewed by the court as a serious infraction of its orders, justifying appropriate sanctions unless exceptional circumstances justify its failure. Upon learning that there are any additional relevant documents in its possession or under its control which have not been produced or identified, a defendant is under an obligation to promptly make known the existence of the documents (including the reason for its failure) and submit the documents to the depository or, if withheld under a claim of privilege or protection, identify the documents.

(3) Pleadings, interrogatories, trial transcripts, and similar materials will, to the extent feasible, be stored in computerized text-readable and searchable format. Depositions will be stored both in the form of text-readable and searchable computer files

and on video-tape. Other documents such as letters, reports, photographs, etc. (including those appended to a deposition) will be "imaged" under a contract with DocuQuest approved by the court in Order No. 4 and then made available to litigants on CD-ROM disks or other suitable media unless, because of the nature of the materials, they are unlikely to be used in other than a single case (e.g., medical history records of a particular plaintiff).

(4) A summary will be prepared by Plaintiffs' National Steering Committee and reviewed by the defendants, which identifies by number and describes (in neutral words that would be suitable for use by a court in preparing a list of exhibits) the various documents. This summary will be prepared in a computerized data-base format and made available to all parties, who then may add private, work-product comments as separate fields in their own copy of the data-base.

(5) All "protective" orders previously entered in any of the cases part of MDL-926 under Rule 26(c) are (with the exception of those designed to keep confidential the identity and medical condition or history of plaintiffs or putative class members) hereby vacated and voided effective November 15, 1992. Any party seeking to impose restrictions on access to or use of any materials under Rule 26(c) shall file by November 1, 1992, a motion identifying with particularity the materials for which the protection is

sought and the proposed terms and conditions of any such protection. If materials are subject to a protective order entered by another court in a case that is not part of MDL-926, the affected parties are expected to waive, to the extent feasible, any rights under such orders to keep such materials confidential and, if necessary, to seek relief from the court in which the protective order was entered. To the extent any materials remain or become subject to a protective order, that fact will be indicated in a separate field on the summary described in paragraph (4) above.

(6) Tina J. Crowe, Supervisor of the Depository, will prepare and make available before December 1, 1992, an informational booklet explaining how materials can be obtained from the depository.

(7) Each party shall preserve all documents and other records and exhibits potentially relevant to the subject matter of this litigation. Subject to further order of the court, parties may continue routine erasures of computerized data pursuant to existing program, but they shall (A) notify opposing counsel about such programs and (B) preserve any printouts of such data. Requests for relief from this directive will receive prompt attention from the court. The parties are to confer and attempt to agree on arrangements for the preservation or disposition of explanted/removed materials.

(f) Depositions.

(1) **Schedule.**

(A) **National Defendants.** Depositions of current and former employees of the "National" defendants may commence after October 15, 1992, and are to be completed by March 31, 1993. These should be taken on the assumption they may be used as trial testimony. They should be recorded both on video-tape and stenographically, with a computer disk in text-readable form also being obtained. The direct examination should be made by the party who would most likely be presenting the testimony of that person at trial. If a potential deponent has not previously testified in a deposition or at trial, it may be appropriate to arrange for a "discovery" deposition by opposing parties prior to the "trial-type" deposition.

(B) **Plaintiffs.** Depositions of plaintiffs may commence after December 1, 1992. For most of these, the principal purpose will be for "discovery" purposes and will likely be noticed by defendants after the plaintiff has answered interrogatories providing "core information" about the plaintiff's condition and claims of damage. The parties are given leave to conduct these depositions by video-tape recording (provided a stenographic record is also made), but there is no requirement for video-taping. No cut-off date can be established at this point in view of the potential for additional cases and the lack of certainty as to trial dates.

(C) **National Experts.** Depositions of "national" experts – those whose testimony may be used in different trials around the country – may commence after March 31, 1993, and should be completed by May 31, 1993. These should be taken on the assumption they may be used as trial testimony. They should be recorded both on video-tape and stenographically, with a computer disk in text-readable form also being obtained. The direct examination should be made by the party who would most likely be presenting the testimony of that person at trial. If a potential deponent has not previously testified in a deposition or at trial, it may be appropriate to arrange for a "discovery" deposition by opposing parties prior to the "trial-type" deposition. It is recognized that supplemental depositions may be needed from time to time, for example if there is a change in the state-of-knowledge regarding implants and their consequences.

(D) **Plastic Surgeons; Hospitals.** Depositions of surgeons and hospital personnel involved in implant or explant/removal procedures, some of whom may be named as defendants in some cases, may commence after May 31, 1993. These depositions are likely to have two phases or aspects – first, general information that is not plaintiff-specific (e.g., education, what they knew or were told about implant materials and when, what they usually

advised patients, etc.) and second, particular information that is plaintiff-specific. It is anticipated that this general information would be obtained in a trial-type video-taped deposition for potential use in all appropriate cases and that this could be accomplished during Summer 1993. Some plaintiff-specific depositions might be conducted as early as Summer 1993, but the time required for all of these will depend upon the number of procedures performed by the deponent and the potential trial dates for a particular plaintiff.

(E) **Treating Physicians.** Depositions of physicians who have treated plaintiffs may commence in some cases as early as June 1993. The time required to complete these will be set as potential trial dates are determined for particular cases.

(F) **Defendant's Examining or Consulting Physicians.** Depositions of physicians who examine plaintiffs under Rule 35 on the request of a defendant or who may otherwise be called by a defendant to express opinions regrading a plaintiff's condition should ordinarily be taken after the depositions of the plaintiff's treating physicians. In some cases this might occur as early as August 1993. The time required to complete these will be set as potential trial dates are determined for particular cases.

(G) **Other Witnesses.** Depositions of other persons (e.g., members of plaintiff's family) will be scheduled based on the potential dates of particular cases. It is not expected that any of these would commence before June 1993. If a deposition is needed to provide the evidentiary foundation for admissibility of documents (e.g., under Evidence Rule 803(6) as evidence of the truth of assertions contained in a business record), it is expected that, to save costs, this would be accomplished either by a telephone deposition or by a deposition under Rule 31.

(2) **Method of Examination.** When taking depositions for potential use in a number of cases: (A) start with full examination (direct, cross, and redirect) on the matters of general interest before proceeding into any additional interrogation that is plaintiff-specific; (B) avoid identifying items such as "I'm Mary Smith and I'm representing Jane Doe" that could be confusing when the deposition is used in other cases; and (C) do not repeat examination merely to make it specific to a particular case. For example, if Dr. Don Jones testifies that he didn't tell *any* of his patients that there was a risk that X might happen, don't ask him for the same information about each individual plaintiff.

(3) **Objections.** Even in depositions taken primarily for use at trial, it is rarely necessary to state objections to questions during the deposition. Most objections can –

and should – be made for the first time at trial when a deposition is offered. Any objections that are made during the deposition must be stated concisely and in a non-argumentative and non-suggestive manner, such as would be appropriate if the examination was conducted before a judicial officer. A party may instruct a deponent not to answer a question only when necessary to preserve a privilege, to enforce a limitation on evidence imposed by the court, or to present a motion under Rule 30(d).

(4) **Number of Examiners.** Counsel should exercise self-restraint by not attending depositions that can be fairly conducted by others having a similar interest. One or two attorneys are to be designated by each side to conduct the principal examination of the deponent. While other counsel may ask additional questions, these should be limited to matters not already covered, and it is preferable that these additional questions be asked by the same counsel who have conducted the prior examination. It will be permissible to take periodic recesses during a deposition in order for examining counsel to consult with their colleagues about additional lines of examination, but such recesses should not be used to "coach" the deponent.

(5) **Disputes during Depositions.** Counsel should attempt to resolve disputes arising during depositions without need for court intervention. Disputes that cannot be so resolved may, if they might result in the need to conduct a supplemental deposition,

be raised with this court by telephone, either to the undersigned (205-731-1709) or to Magistrate Judge Elizabeth Campbell (205-731-0364). It is expected that disputes between the parties should be addressed to this court rather than to the district court in which the deposition is being conducted, and that the undersigned will exercise the powers conferred by 28 U.S.C. § 1407(b) to deal with disputes involving non-party deponents.

(6) **Use at Trial.** A deposition taken pursuant to this plan (including, when filed in the document depository, depositions previously taken in these cases and depositions previously or subsequently taken in any other silicone gel implant litigation in federal or state courts) shall be considered as satisfying the requirements of Rule 32(a) for use at trial in any federal court action involving silicone gel implants (subject to meeting the conditions stated in one of the numbered paragraphs of that subdivision) against any entity that –

(A) at the time the deposition is taken is a party in any case then consolidated in this court under CV 92-P-10000-S, or

(B) after the deposition is taken becomes a party in any case consolidated in this court under CV 92-P-10000-S, unless within 45 days after first becoming a party it files with this court a written request that one or more specifically identified depositions not be used in the case(s) in which it is a

party. If such a request is filed, other parties wanting to use the deposition(s) in the case may thereafter notice the deponent for a supplemental deposition, including one by telephone or on written questions under Rule 31. In such depositions the deponent should first be asked whether he or she reaffirms the testimony previously given. If the answer is "yes," further examination of the deponent should be limited to issues and items not covered in the original deposition.

The parties to this litigation are hereby ENJOINED from raising, with respect to any deposition usable against them in federal court actions, any objection in any state court action involving silicone gel implants to the use of the deposition based upon the fact that the deposition was not taken in the state court action. Any request for relief from this injunction must be filed with this court within 30 days from the date the deposition is filed in the depository or from the date it first becomes a party in this litigation.

These provisions do not preclude objections to use of a deposition premised upon the availability of the deponent to be called in person, nor do they preclude objections to the admissibility of particular items of testimony in a deposition on evidentiary grounds such as relevance, hearsay, etc.

To facilitate usability of depositions in state court actions involving entities that are not and may never be parties in the federal

cases, the parties are encouraged, if no other procedures have been established by the state courts, to issue "cross notices" of depositions to the additional state-court parties.

(g) Interrogatories.

(1) **To Plaintiffs.** The National Defendants will, after conferring with Plaintiffs' National Steering Committee, file by October 15, 1992, a single master set of interrogatories and document requests designed to elicit (to the extent not previously obtained) from each named plaintiff (but not from putative class members) "core" information needed to conduct an efficient deposition of the plaintiff. While plaintiffs may be asked to identify potential "fact" witnesses relating to liability or damage claims, they are not to be asked so-called contention interrogatories. Plaintiffs are to serve answers and make documents available by November 15, 1992 (or within 30 days after the case is filed in, removed to, or transferred to this court as a part of CV 92-P-10000-S), but the parties are granted leave to agree (and are expected to agree) on appropriate extensions of time, taking into account the number of plaintiffs that a particular law firm may be representing and the time when counsel would realistically be ready to proceed with a deposition of a particular plaintiff.

(2) **To Defendants.** Plaintiffs' National Steering Committee will, after conferring with counsel for each of the National Defendants, serve by March 31, 1993, a set of

interrogatories directed to that defendant. These interrogatories should be limited to questions eliciting information (e.g., its relationship to other defendants and trade organizations to which the defendant belongs) that might reasonably be expected to be used as evidence at a trial. So-called contention interrogatories will not be allowed. Given the limited purpose of these interrogatories, defendants should be able to serve their answers within 30 days after being served with the interrogatories.

(h) **Additional Discovery Requests.** The parties will confer concerning, and attempt in good faith to agree upon, any additional discovery requests not described above. The court expects that any such requests should not seek information already obtained and available from the depository absent good cause to believe that the available information is inadequate or incorrect.

(i) **Deadlines Imposed by Other Courts.** Orders issued by other courts imposing dates for initiation or completion of discovery are, when a case is removed or transferred to this court, vacated and replaced by the schedule provided in this order.

(j) **Exceptional Cases.** Any party may move for relief from the prescribed discovery schedule when merited by special circumstances, such when a plaintiff is "in extremis" or to obtain information pertinent to critical preliminary issues (e.g., forum nons convenience issues respecting claims by foreign plaintiffs).

(k) **Special Master.** Pursuant to Rule 53(a), the court hereby appoints Francis E. McGovern

as Special Master for the purpose of assisting this court in the fair and efficient coordination of discovery conducted in federal court with that conducted in the various state courts in which similar cases are or may hereafter be filed.

8. **Class Actions.** In Order No. 3 this court extended indefinitely the time within which putative class members can elect to exclude themselves from the class action that was previously certified by the United States District Court for the Southern District of Ohio in Donna Dante et al. v. Dow Corning Corp. et al, (No. 1:92-057), which is now pending in this court as Case No. CV 92-P-10060-S. This court has not determined whether the class certification in Dante will be retained, vacated, or modified, or whether a class should be certified in any of the other cases in which such a request has been or may hereafter be made. Such decisions will be made at a future date, with appropriate notification being given to persons to be affected thereby. Under current law, statutes of limitations are probably considered as tolled for members of the Dante class during the pendency of the class certification.

9. **Trial(s).** This court has not yet made any determination whether any cases should be consolidated for trial, whether some issues should be tried separately from others, whether any cases should be transferred to this court under 28 U.S.C. § 1404 or 1406, etc. For planning purposes, however, it is anticipated that some cases might be ready for trial on liability and damages as early as – but, absent extenuating circumstances, not earlier than – Fall 1993. There is the possibility that some special

issues, such as the responsibility of one defendant for the actions of another, might be ready for separate trial prior to that time.

This the 15th day of September, 1992.

/s/ Sam C. Pointer, Jr.
United States District Judge

Attachments:

A – Abbreviated Order for Filing in Individual Cases
B – Information Concerning National Defendants
C – Plaintiffs' National Steering Committee

EXHIBIT C

Plaintiffs' National Steering Committee

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Waite, Schneider, Bayless & Chesley
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Plaintiffs' National Steering Committee (cont'd)

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Fax: 503-295-3720

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re: SILICONE GEL BREAST IMPLANT PRODUCTS LIABILITY LITIGATION (MDL 926)	)	Master File No. CV 92-P-10000-S
HEIDI LINDSEY, et al., Plaintiffs, -vs.- DOW CORNING CORP., et al., Defendants.	)	Civil Action No. CV 94-P-11558-S

ORDER NO. 15

(Granting Preliminary Approval to Settlement Agreement, Conditionally Certifying Settlement Class, Approving Notice, and Scheduling Fairness Hearing)

(Filed Apr. 1, 1994)

After reviewing the Breast Implant Litigation Settlement Agreement ("Settlement Agreement") submitted by the parties in *Lindsey, et al., v. Dow Corning Corp., et al.*, Civil Action No. CV 94-P-11558-S (the "Lindsey action"), and being satisfied that, with the modifications effected by this order, the proposed settlement appears to meet the applicable criteria for preliminary approval, the Court preliminarily approves the proposed class action settlement described in the Settlement Agreement and provisionally orders, subject to further alteration or amendment under Fed. R. Civ. P. 23(c), as follows:

1. The Lindsay action is certified as a class action for settlement purposes under Fed. R. Civ. P. 23(a), 23(b)(3), and 23(c).

(a) The Lindsay action will be maintained on behalf of a non-mandatory ("opt-out") Plaintiff Settlement Class (the "Class") that, except as provided in paragraph 1(b), consists of –

(1) all persons, wherever located, who have been implanted before June 1, 1993, with one or more included Breast Implants (or with any Breast implants made with any Included Breast Implant materials), whether or not such Breast Implants have been or may later be removed, with respect to any existing or future claim, known or unknown, accrued or unaccrued, against a Settling Defendant or Released Party for their own personal injury or death that may be asserted as due in whole or part to any breast implant;

(2) every child, wherever located, born before April 1, 1994, whose natural Mother is a person described in paragraph 1(a)(1) and who was born after the date his or her Mother had a breast implant, with respect to any existing or future claim, known or unknown, accrued or unaccrued, against a Settling Defendant or Released Party for his or her own personal injury or death that may be asserted as due in whole or part to his or her Mother's having had a breast implant; and

(3) all persons or entities (including estates, representatives, spouses, children, relatives, and "significant others"), wherever located, with respect to any existing or future claim, known or unknown, accrued or unaccrued, against a Settling Defendant or Released Party that they may assert independently or derivatively because of their personal relationship to a person described in paragraph 1(a)(1) or 1(a)(2).

(b) Excluded from the Class are the following:

(1) breast implant recipients all of whose breast implants are identified as having been manufactured or distributed by McGhan Medical Corp., INAMED Corporation, Minnesota Mining and Manufacturing Co. ("3M"), Porex Medical Technologies Corp. (or related companies), or by Koken Co., Ltd., or other foreign manufacturers not listed in Exhibit A or B to this Order;

(2) breast implant recipients who are not citizens of the United States if (A) all of their breast implantations were performed outside the United States and (B) they have received any compensation for breast implant injuries or expenses under the laws or procedures of another country;

(3) breast implant recipients who, before June 17, 1994, shall have separately settled with a Settling Defendant, providing a general release of claims related to breast implants, unless (A) they were not

represented by counsel in such settlement and the settlement involved a payment of less than $15,000 or (B) they demonstrate by clear and convincing evidence that their settlement was induced by fraud by a Settling Defendant;

(4) breast implant recipients who, before June 17, 1994, shall have obtained and collected a judgment against a Settling Defendant for a breast implant claim or shall have had a final judgment after a trial on the merits entered against them on a breast implant claim in favor of a Settling Defendant;

(5) breast implant recipients who elect to exclude themselves from the Class by return of a completed Exclusion Form, received or postmarked no later than June 17, 1994; and

(6) any person or entity described in paragraph 1(a)(2) or 1(a)(3) whose status as a class member depends on class membership of a recipient excluded under paragraph 1(b)(1) through 1(b)(5).

(c) For purposes of this Order, the terms –

(1) "Breast Implant" means any mammary prosthesis containing or consisting of silicone, silicone gel, or saline; it does not include a silicone injection. The terms "Included Breast Implants" means Breast Implants manufactured, distributed, designed, fabricated, sold, produced, or otherwise placed in the stream of commerce by any Settling Defendant or Released Party.

(2) "Breast Implant Materials" means materials, products, or components used in the manufacture of a Breast Implant. The term "Included Breast Implant Materials" means Breast Implant Materials manufactured, distributed, designed, fabricated, sold, produced, or otherwise placed in the stream of commerce by any Settling Defendant or Released Party.

(3) "Breast Implant Recipient" means a person in whose body one or more Breast Implants were implanted before June 1, 1993, whether or not already or later removed,

(4) "Settling Defendants" means the companies listed in Exhibit A to this Order, with such additions or corrections as may be approved by the court.

(5) "Released Parties" means the Settling Defendants; the individuals and entities listed in Exhibit B to this Order (with such additions or corrections as may be a approved by the court); their respective present and former foreign and domestic parents, subsidiaries, and affiliates; their respective foreign and domestic predecessors, successors, sales representatives, independent sales representatives, distributors, transferees, insurers, and assigns; and their respective present, former, and subsequent officers, directors, agents, servants, proprietors, owners, shareholders, and employees, except that the term "Released parties" –

(A) does not include doctors, hospitals, and other health-care providers who furnished medical services directly to a Class Member unless they are specifically named in Exhibit B, and

(B) does not include doctors specifically named in Exhibit B with respect to claims against them based upon their furnishing medical services directly to a Class Member.

(6) "Bioplasty Defendants" means Bioplasty, Inc.; Bio-Manufacturing, Inc.; Utoplasty, Inc.; and New Uroplasty, Inc.

"Mentor Defendants" means Mentor Corporation; Mentor Polymer Technologies, Inc.; Mentor OOO, Inc.; Mentor H/S, Inc.; Mentor Urology, Inc.; Mentor International, Inc.; and Tecknar Corp.; and their respective predecessors, successors, parent and subsidiary companies and divisions, and current and former attorneys, officers, directors, agents, distributors, sales agents, and employees.

(d) The class claims that are certified to be maintained on behalf of Class Members are limited to those against any of the Settling Defendants and the Released Parties and related to or involving breast implants.

(1) Claims against the Bioplasty or Mentor Defendants, although not certified as class claims in the Lindsey action, are generally precluded as a result of bankruptcy proceedings involving the Bioplasty Defendants in United States

Bankruptcy Court in Minnesota, BK 4-93-2600, BK 4-93-2603, and BK 4-93-2604, and as a result of the mandatory settlement with the Mentor Defendants approved in Order No. 14 in CV 93-P-11433 and in Master File No. CV 92-P-10000-S.

(2) Claims against any other manufacturer, distributor, or supplier of Breast Implants or Breast Implant Materials, or against physicians, hospitals, or other healthcare providers who are not Released Parties are not certified as class claims by this Order and are not released or dismissed under the Settlement Agreement.

(e) Subject to further orders of the Court –

(1) Plaintiffs Heidi Lindsey, Cynthia Bullock, Margaret Abner, Dorothy Dressler, Rita Thompson, Donna Dante, and Joy Bryan are designated as Representative Plaintiffs for the Class.

(2) The following attorneys are appointed as Settlement Class Counsel and as the initial members of the Settlement Committee: Margaret Moses Branch; Elizabeth J. Cabraser; Stanley M. Chesley; Michael T. Gallagher; and Ralph I. Knowles, Jr.

The Court reserves the power to appoint additional and substitute Representative Plaintiffs, Settlement Class counsel, and Settlement Committee Members and to define appropriate subclasses, including the designation of

representatives and appointment of counsel for such subclasses as necessary.

(f) Confirmation and permanent certification of the Class is conditioned upon a showing, to the court's satisfaction, that the proposed settlement described in the Settlement Agreement is fair, adequate, and reasonable, is in the best interest of the class, and should be approved under Fed. R. Civ. P. 23(e). If the proposed settlement is not approved, the provisional class certification will be vacated, the Plaintiffs and Settling Defendants will retain all rights to support or oppose certification of the Lindsey action for litigation purposes, and provisional certification may not be used by plaintiffs or defendants in support of any argument for or against certification of any other class. Neither this provisional certification nor, if ultimately approved, the permanent certification of the Class to consummate the Settlement Agreement constitutes a determination by the court as to whether a plaintiff class should be certified for purposes of trial or settlement with any other person or entity involved in the manufacture, distribution, or implantation of Breast Implants or Breast Implant Materials.

(g) The effect of class allegation in the Lindsey action on class certification in *Dante, et al. v. Dow Corning Corp., et al.*, CV 92-P-10060-S, ("the Dante action") and in any other action commenced in or removed to federal court as a class action shall be as follows:

(1) Thirty days after an order confirming and permanently certifying a class in the Lindsey action has (after any

appeals) become final, (A) class certification in the Dante action shall be deemed to be vacated, (B) proposed class certification in any other federal action then pending shall be deemed as denied, and (C) all persons covered by the class definition in the Lindsey action shall be deemed as members of the Lindsey class unless they opt out in accordance with the procedures specified for the Lindsey action, without regard to whether they were members of the Dante class, had opted out of the Dante class, or were putative members of another proposed class. Provisional or final certification of a class in the Lindsey action does not affect the class action order entered with respect to the Mentor Defendants as approved in Order No. 14 in CV 93-P-11433 and in Master File No. CV 92-P-10000-S.

(2) Statutes of limitation and repose shall be deemed to have been suspended or tolled for any person covered by the class definition in the Dante action from January 24, 1992, the date of commencement of the Dante action, until the earliest of (A) the date such person opted out of the Dante action, (B) 30 days after the date such person opts out of the Lindsey action, or (C) the date an order confirming and permanently certifying a class in the Lindsey action has (after any appeals) become final.

(3) Statutes of limitation and repose shall be deemed to have been suspended or tolled for any person covered by the

class definition in the Lindsey action from March 23, 1994, the date of commencement of the Lindsey action, until 30 days after the earlier of (A) the date such person opts out of the Lindsey action or (B) the date the provisional class certification in the Lindsey action is vacated or is modified to eliminate such persons as a class member.

(4) Statutes of limitation and repose shall be deemed to have been suspended or tolled for any person covered by the proposed class definition in any other case (other than the Dante and Lindsey actions) brought in federal court from the date of commencement of such case until the earlier of (A) the date certification of such class has been denied, (B) 30 days after the date such person opts out of the Lindsey action, or (C) the date an order confirming and permanently certifying a class in the Lindsey action has (after any appeals) become final.

2. The terms of the Settlement Agreement are provisionally approved, with the following implementing orders and modifications:

(a) The amount to be paid into Designated Fund VI, which is to cover all fees and expenses of attorneys (whether court-appointed or privately-retained) and all costs of class notice and settlement administration, is established at 25% of the total settlement amounts and will be paid as payments are made by Settling Defendants throughout the period of the Settlement Agreement, approximately 15% from the amounts prescribed in the Settlement Agreement for

Designated Funds I through V and approximately 30% from the amounts prescribed in the Settlement Agreement for the Disease Compensation Program. The court will by subsequent order establish procedures for making and paying claims under Designated Fund VI, and if Designated Fund VI exceeds the fees, expenses, and costs approved by the court, the excess will be distributed to Class Members as the court may determine, after consulting with the Claims Administrator and Plaintiffs' Settlement Counsel. The funds recovered under this settlement are not subject to any additional charge or assessment under Order No. 13 in CV 92-P-10000-S, which order, however, otherwise continues in effect except that moneys already or later collected under Order No. 13, shall be added to, administered as part of, and disbursed under the procedures to be established for, Designated Fund VI.

(b) Judge Ann Tyrrell Cochran of Houston, Texas, is appointed as Claims Administrator, effective April 7, 1994, under the authority of Federal Rule of Civil Procedure 53 and in the exercise of the court's general powers and responsibilities over class action settlements. Her actions as Claims Administrator (and those of her employees or agents) in collecting, collating, processing, evaluating, and paying claims will constitute judicial actions of this court and be protected to the maximum extent allowable by law, by the doctrine of judicial immunity.

(c) In the event of direct conflict between the terms of the Notice approved by the court and the terms of the Settlement Agreement, the Notice will take precedence.

(d) The provisions of section III.E of the Settlement Agreement, relating to Foreign Claimants, will be modified as follows:

(1) A "Foreign Claimant" means a breast implant recipient who is otherwise a member of the Lindsey Class if (A) such person is not a citizen of the United States and (B) all of such person's breast implants were implanted outside the United States.

(2) A foreign Claimant may opt out of the Lindsey Class by completing and returning the Exclusion Form by June 17, 1994. by so doing, the Foreign Claimant will preserve such rights, if any, that the person may have to file or pursue a claim related to breast implants against the Settling Defendants and Released Parties in the federal and state courts of the United States or in the courts or administrative tribunals of another country.

(3) A Foreign Claimant who does not opt out of the Lindsey Class by June 17, 1994, will, if such person fails to make a claim or register in the Lindsey action by December 1, 1994, not be entitled to any benefits under the Lindsey settlement, will be precluded from filing or pursuing a claim related to breast implants against the Settling Defendants and Released Parties in the federal and state courts of the United States, but will have such rights, if any, as that person may have to file or pursue such claims against the Settling Defendants and

Released Parties in the carts or administrative tribunals of other countries.

(4) A Foreign Claimant who does not opt out of the Lindsey Class by June 17, 1994, will, if such person makes a claim or registers in the Lindsey action by December 1, 1994, be entitled to participate in benefits provided to Lindsey Class Members (exclusive of benefits under Designated Funds I through V) subject to the following:

(A) The Foreign Claimant may participate in benefits under the Disease Compensation Program, but the amount of benefits to be paid to such person is subject to being adjusted downward by the court, relative to similar amounts paid to other Class Members, (i) to account for differences between compensatory awards typically recovered in federal and state courts of the United States and those obtained in the courts or tribunals of the country where the breast implants occurred and (ii) to assure that the total amounts paid to Foreign Claimants under the Disease Compensation Program do not exceed the maximum amount set aside for such persons under paragraph III.E.2 of the Settlement Agreement.

(B) A Foreign Claimant affected by a potential downward adjustment under paragraph 2(d)(4)(A) of this Order will be so notified and at that time afforded the opportunity to opt

out of the Lindsey Class, subject to repayment of any amounts already paid to such person from the settlement funds.

(C) A Foreign Claimant who opts out under paragraph 2(d)(4)(B) may pursue such rights, if any, as that person may have to file or pursue such claims respecting breast implants against the Settling Defendants and Released Parties in the courts or administrative tribunals of other countries, but will be precluded any such claim in the federal and state courts of the United States. Moneys tentatively allocated under this settlement to Foreign Claimants who so opt out will be reallocated among other Class Members, including remaining Foreign Claimants, as the court may direct.

(e) Notwithstanding language of the Settlement Agreement that at various places (e.g., guidelines for payments under Fund I, relating the Medical Diagnostic/Evaluation Fund) indicates that Settlement Class Counsel are to make determinations relating to the allocation of funds among potentially competing Class Members, such decisions will be the responsibility of the court after consultation with the Class Administrator. In view of the possibility of disputes that may place some Class Members in conflict or competition with other Class Members, the role of Settlement Class Counsel in such matters will be to provide advise to the Claims Administrator and court.

(f) Through further orders, the court will, from time to time, establish other deadlines and procedures as may be called for in the Settlement Agreement.

(g) The name, address, and other identifying information of Class Members (including those who call the Settlement Information Line and those who opt out of the settlement) will be kept confidential and private except to the extent needed for proper administration of the terms of the settlement.

3. The court approves the Notice Program attached as Exhibit C to this Order and the contents of the attached abbreviated Notice to be used in selected newspapers and magazines. The court will subsequently approve a detailed Breast Implant Litigation Settlement Notice and Forms, for mailing to Class Members. Dissemination of these notices, in conjunction with the other steps set forth in the Notice Program, constitutes the best notice practicable under the circumstances, and, when performed, should provide due and sufficient notice to all members of the class and satisfy the requirements of due process and Fed. R. Civ. P. 23. The parties shall use their best efforts to commence the Notice Program by April 11, 1994. The parties shall submit a certificate describing and certifying their compliance with the notice requirements of this Order by July 17, 1994. Any defendant desiring to publish, mail, or otherwise disseminate court-approved notices at times or in locations, publications, and media in addition to those prescribed in the Notice Program may do so, but the cost will be borne by that defendant

and not reduce the defendant's payment obligations under the settlement.

(4) The court will hold a formal fairness hearing (the "fairness hearing") to determine whether to grant final approval to the proposed Settlement Agreement, as fair, adequate, and reasonable, to confirm or modify certification of the Settlement Class, and to issue its Final Order and Judgment thereon. This hearing will be held on August 18, 1994, at 9:00 a.m., and at the United States Courthouse, 1729 Fifth Avenue North, Birmingham Alabama. The hearing may, from time to time and without further notice to the class, be moved to another facility in Birmingham or continued or adjourned by the court.

(a) To maintain orderly proceedings and to afford a reasonable opportunity to be heard to those who wish it, any Class Member wishing to appear in person, individually or through counsel, and be heard at the fairness hearing must submit a written notice of intent to appear, postmarked no later than June 17, 1994, mailed to the Post Office Box established by the parties for that purpose, as set forth in the attached Notices.

(b) Any member of the Settlement Class wishing to submit a written comment to support or oppose any aspect of the Settlement Agreement, the certification of the Settlement Class, or the Settlement approval process, may do so in writing, without the necessity of retaining counsel or making any formal appearance, provided such written comments are postmarked no later than June 17, 1994, and mailed to the Post Office

box established for that purpose as set forth in the attached Notices.

(c) Members of the Settlement Class may exclude themselves (opt out) from the Class by following the procedures set forth in the Notices, including the individual signature and return of the Exclusion Form to the Post Office Box provided it is received or postmarked no later than June 17, 1994.

(d) The Settling Parties shall submit their opening papers in support of final settlement approval by May 17, 1994, and shall submit a report on the status of the claims and reply to any settlement comments or objections after the opt-out and objection deadlines, and in advance of the fairness hearing.

5. The Settlement Agreement, with Exhibits, shall be made available for public inspection in the Clerk's office during regular business hours.

6. In aid of the court's jurisdiction over the Settlement Class provisionally certified in this Order, and to assure the fair and orderly conduct and completion of the settlement consideration process described in this Order and the approved Notices, the court hereby:

(a) temporarily stays and suspends, pending further order, any and all class certification or class notice proceedings in any and all federal and state civil actions to the extent that any classes proposed or certified in such actions purport to include persons and claims included in the complaint in the Lindsey action, in the Settlement Agreement, and in the class definition provisionally approved in this order; and

(b) temporarily enjoins the commencement of trial in any federal or state court during the period from June 16, 1994, to August 18, 1994, of any breast implant action against a Settling Defendant or Released Party by any Class Member who shall not have timely elected to be excluded from the Settlement Class.

This the 1st day of April, 1994.

/s/ Sam C. Pointer, Jr.
Sam C. Pointer, Jr.
United States District Judge

EXHIBIT A
Settling Defendants

Aesthetech Corporations
American Heyer-Schulte Corporation
f/k/a Heyer-Schulte Corporation
American Hospital Supply Corporation
Baxter Healthcare Corporation
Baxter International, Inc.
Bristol-Myers Squibb Canada, Inc.
Bristol-Myers Squibb Company
Cabor Medical Corporation
CBI Medical, Inc.
a/k/a CBI Medical Electronics, Inc.
CooperSurgical, Inc.
CooperVision, Inc.
CUI Corporation
CVI Merger Corp.

CV Sub 1987, Inc.
Dow Corning Corporation
Dow Corning STI
Dow Corning Wright Corporation
Dow Corning Wright/Medical Materials
Hazelton Biotechnologies, Inc.
Hazelton Corporation
Hazelton Washington, Inc.
HRP, Inc.
Linvatec Corporation
Markham Medical Association
Markham Medical International, Inc.
Markham Surgical Specialties
Mark/M Resources, Inc.
MEC Subsidiary Corporation
f/k/a Surgitek, Inc.
Mark/M Surgical
Medical Engineering Corporation
Natural "Y" Surgical Specialties, Incorporated
Poly Plastic Silicone Products, Inc.
Sirod Corporation
Summit Medical Corporation
Surgitek, Inc.
Edward Weck, Incorporated
Edward Weck & Company, Inc.
Wright Manufacturing, Inc.
Zimmer, Inc.
Zimmer International, Ltd.

EXHIBIT B
Released Parties

ACME Engineering
Louis Argenta
Franklin L. Ashley
Baxter Acquisition Sub., Inc.
Baxter Corporation
Baxter Travenol Laboratories, Inc.
Baxter World Trade Corporation
John Beernick
Bio Manufacturing, Inc.
Bioplasty, Inc.
Laurence Birnbaum
Robert Bishop
Ralph Blocksma
Garry S. Brody
Boyd Burkhardt
Angelo Cappozzi
Thomas Cronin
Eugene Courtiss
Corning Incorporated
CVI Merger Corp.
The Dow Chemical Company
Edwards Laboratories, Inc.
Derwood Faries
Vicki Galati
Frank Garow
Ben Gregory
John Hartley
Hazelton Research Corporation
Hazelton Wisconsin, Inc.
Robert J. Heibling

Richard P. Jobs
Harold Markham
Jacqueline Markham
Lottie Markham
Anita Kost McAteer
Kathy Montgomery
Real Lappierre
W. John Pangman, II
Vincent R. Pennial
Marie Pietsch
Robert Reeder
W. Ian Rogers
Diran M. Seropian
Schulte Medical Products
H.E. Sterling
Kuros Tabari
Travenol Laboratories, Inc.
Uroplasty, Inc.
Charles Vinnick
Kurt Wagner
John L. Williams
Wright Medical Technologies

EXHIBIT C
Notice Program

The Federal Rules of Civil Procedure require that the Court direct to the members of the class the best practicable notice under the circumstances. Unlike some other class actions, in this litigation the primary Class Members

– those with breast implants – know whether they have been exposed to the products at issue, breast implants. Furthermore, this litigation has been the subject of extensive media attention over the last 18 months, with the result that most putative Class Members in this country are probably aware of the litigation if not its potential settlement. That more than 40,000 phone calls were received in the first week since Plaintiffs' Settlement Counsel established a toll-free information line demonstrates the degree of awareness among implant recipients. This Notice Program has been designed to provide, in the light of these circumstances, due and sufficient notice and satisfy the requirements of due process and Fed. R. Civ. P. 23, without wasteful diminution of settlement funds through excess notification procedures.

The Notice Program consists of several components designed to assure the maximum reasonably practicable notice to the settlement class. The purpose will be to inform the members of the class of the terms of the proposed settlement, the manner in which the settlement may effect their rights, the operative deadlines for opting out of or objecting to the settlement, and the procedure for obtaining further information and for filing claims.

The Notice Program takes into consideration the nature of the class membership (*i.e.*, age, gender, income levels, and geographic distribution of the class) and is specifically targeted to reach the maximum number of Class Members, in the United States and other countries, without undue and unwarranted expenditures. The program includes the direct mailing of a complete Notice package to known Class Members, along with an "early alert" media campaign designed (through publication of

a short form Notice, television advertisement, and a public relations effort) to inform other Class Members of the essentials of the Settlement and the procedure for obtaining detailed additional information that will assist them in evaluating their rights and options. The components of the Notice Program are summarized below:

1. Individual Notice. All Class Members whose names and addresses are known or can be determined through reasonable effort will receive a Notice package by first class mail. The package will consist of a Settlement Notice that describes in detail the terms of the proposed settlement and the rights and options of Class Members, a "question and answer" booklet that answers in simple language the most common questions about the settlement, and the registration, claim, and exclusion forms. The full Notice is a combination notice under Fed. R. Civ. P. 23(c) and (e) and advises the class members of:

- the proposed class action and the proposed Settlement
- the procedures for opting out of the class
- the effect of remaining in the class
- the process for obtaining a copy of the Settlement Agreement
- the procedures for registration and filing claims.

Plaintiffs' Settlement Counsel have established a toll-free telephone information line that Class Members may call to request the Notice package and a post office box to which Class Members may write to request a Notice package. The telephone number and the post office box address will be disseminated through advertisements and a public relations effort as described below.

2. Notice by Publication/Advertisements in Print and Broadcast Media. Advertisements will be placed in various newspapers and magazines in the media markets throughout the United States that should reach the virtually all potential members of the class within the United States. The advertisements will advise potential Class Members of the proposed class action and settlement, explain the essential terms of the settlement, outline the procedures and deadlines for opting out, inform Class Members as to critical dates in the settlement approval process, and advise Class Members how to obtain detailed information about the Settlement (*i.e.*, the full Notice package). In some publications it may be more appropriate to publish an abbreviated notice merely informing Class Members of the existence of the proposed settlement and the procedure for obtaining the full Notice package. Advertisements also will be placed on local and network television stations, informing Class Members of the proposed settlement, the fact that they must act by a court-established deadline to preserve their rights, and how to obtain the full Notice package.

3. Public Relations and Education. A media outreach effort will be conducted to educate the breast implant population about the settlement. Press conferences will be held to announce the Settlement. A press kit will be distributed to major U.S. newspapers and a video news release will be distributed to the television media regarding the settlement. The press conferences and distribution of press materials and news releases are intended to generate further media coverage that will provide information to Class Members of their basic rights and options under the settlement and instruct

Class Members how to obtain additional information and the full Notice package. This segment of the Notice program may include the preparation and distribution of "radio actualities" (interview quotes that radio stations can use as part of newscasts).

4. Direct Marketing/Communications with the Medical Establishment and Support Groups/Communications with Courts and Lawyers. The medical community has regular contact with the implant population and is therefore an important resource for dissemination of information to the Class Members. Copies of a short form notice and an explanatory letter will be mailed to appropriate medical groups and members of the medical community. Concise informational materials will be mailed to various professional organizations and interest groups that will in turn be able to inform Class Members of the proposed settlement and how to obtain the full Notice package. In addition, a short form notice and an informational letter will be distributed to all state courts in which cases have been filed and to lawyers and/or associations of lawyers that may have clients affected by the settlement.

5. On-Line Computer Networks. The Notice program will take advantage of computer network services in a further effort to inform Class Members of the settlement and their rights. The program will establish bulletin boards and discussion groups on the leading networks and through those avenues will inform the Class Members of their basic rights and obligations under the proposed settlement and the procedure for obtaining the full Notice package.

6. Foreign Communications. Foreign Class Members will be informed of their rights under the settlement and of the deadlines that will affect their rights to opt out of and to participate in the settlement. Identified Foreign Class Members will receive the full Notice package by direct mail in the same manner as United States Class Members. In addition, a media campaign will inform the non-U.S. Class Members of the essential terms of the Settlement (including the rights and options of the class members) and the procedures for obtaining the complete Notice package. The campaign will consist of distribution of press materials to selected press corps and reporters, press conferences in selected foreign cities, placement of advertisements in selected newspapers, and the distribution of informational materials to targeted medical groups and health agencies (subject to the requirements of various foreign governments). It should be noted that should foreign claimants (whether because of not receiving notice or for other reasons) fail to exercise their rights to opt out, to register for benefits, or file claims, they would not be precluded from pursuing any remedies they may have in the country in which their breast implants were implanted.

7. Agents. The Notice program will be implemented by APCO Associates, Inc. under the supervision and jurisdiction of the Court. Details concerning the total cost of the Notice program and the fees to be paid to APCO will be the subject of a separate order to be entered at a later date.

UNITED STATES DISTRICT COURT –
NORTHERN DISTRICT OF ALABAMA
OFFICIAL COURT NOTICE

Breast Implants Products Liability Litigation,
MDL No. 926

ATTENTION

ALL PERSONS WHO HAVE EVER
HAD BREAST IMPLANTS
and their estates, representatives, spouses,
children, and other relatives

PROPOSED BREAST IMPLANT SETTLEMENT

Lawsuits seeking damages for injuries allegedly resulting from breast implants are pending in many state and federal courts. Federal lawsuits are coordinated in the United States District Court for the North District Alabama, before Chief Judge Sam C. Pointer, Jr., as *in re Silicone Gel Breast Implants Products Liability Litigation.* Case No. CV 92-P-10000-S. One of the federal cases, *Lindsey, et al. v. Dow Corning Corp., et al.*, Case No. CV94-P-11558-S, has been conditionally certified as a class action for purposes of a proposed settlement on behalf of persons who may now or later have claims against certain manufacturers of breast implants and suppliers. This settlement includes all breast implants containing silicone, silicone gel, or saline, but does not include silicone injections.

At your written or phone request, you will receive the detailed Breast Implant Litigation Settlement Notice ("Settlement Notice") describing a proposed settlement under which certain manufacturers of breast implants and their suppliers have agreed to pay up to

$3,726,820,000, as needed under the settlement, to receive current and future claims against them. Payments will be made by the settling defendants during a 30-year period into a "Disease Compensation Program" and a series of special "Designated Funds" for the benefit of Class Members. An earlier settlement with the Mentor companies and reorganization of the Bioplasty companies will add approximately $30,000,000 to the settlement funds.

- The Disease Compensation Program has two parts. The "Current Disease Compensation Program" will provide direct compensation to those Class Members who timely make claims for certain defined existing diseases or medical conditions; the "Ongoing Disease Compensation Program" will provide direct compensation to such Class Members not timely filing their claims and to Class Members who during the next 30 years develop one or more of those diseases. The projected net compensation (after reduction for all administrative costs and legal fees) to Class Members with these diseases under either program ranges from $105,000 to $1,400,000, depending on the disease, level of severity or disability, age when first manifested and pre-existing conditions. The Settlement Notice describes the covered diseases, the projected compensation amounts (and the conditions under which these amounts may be increased or decreased), and the procedures for making and documenting claims. The settlement does not require proof that a covered disease was caused by a breast implant.

- The Designated Funds will provide compensation or reimbursement for Class Members' medical evaluations, expenses for removal of Implants ("explantation"). Implant ruptures, and other injuries or emotional distress not constituting a covered disease under the Disease Compensation Program, and for

payment of all administrative expenses and legal fees incurred in the settlement, in claims administration, and in the handling of individual claims.

FAIRNESS HEARING

Judge Pointer will hold a hearing in the United States Courthouse, 1729 Fifth Avenue North, Birmingham, Alabama, on August 18, 1994, at 9:00 a.m. to determine whether the proposed settlement is fair, reasonable, and adequate and should be approved. You do NOT need to attend the hearing. You may comment by mail as this notice explains.

WHO IS A CLASS MEMBER

Except as noted below, the Settlement Class includes

- all persons who have been implanted with one or more breast implants before June 1, 1993 (whether or not later removed)
- all children of such Class Members born after a breast implant and before April 1, 1994, who may now or later have claims for their own personal injury resulting from their mother's breast implants
- all other persons or entities (including estates, representatives, spouses, children, relatives, and "significant others") who, because of a personal relationship with such Class Members, may now or later have claims (such as for loss of services) based on injuries to such Class Members.

Class membership includes all such persons, whether or not they have brought their own lawsuit, whether or not

they are members of (or have excluded themselves from another class action, and whether or not they now suffer from a medical condition associated with a breast implant.

The Settlement Notice describes conditions under which some persons may be excluded from class membership because they have received compensation or reimbursement as a result of settlement, as a result of a judgment in federal or state court, or under the laws or procedures of another country, or because after a trial a final judgment has been rendered against them in favor of a settling defendant.

Also concluded at the present time are persons all of whose breast implants can be identified as having been manufactured or distributed by McGhan Medical Corp., INAMED Corporation, Minnesota Mining and Manufacturing Co. ("3M"), Porok Medical Technologies Corp. (or related companies), or by Kakon Co., Ltd. or other foreign manufacturers, (These companies are met currently parties to the settlement. The Settlement Notice describes circumstances, including the possibility that one or more of them might later become parties to the settlement, under which eligibility to participate in the settlement may be extended to persons with implants manufactured by those companies.)

YOUR RIGHTS AND OPTIONS

Participation in the settlement class is optional, not mandatory, if you come within the class definition, you will automatically be a class member unless you exclude yourself and your family members from the class ("opt

out"). To opt out, you must complete and return an "Exclusion Form," postmarked no later than June 17, 1994.

- If you opt out, you will NOT receive any benefits under the settlement. You would be free to file or pursue breast implant claims against all persons and companies in your own lawsuit at your own expense. Statutes of limitation or repose may limit the time for filing such lawsuits; any tolling of these periods due to pendency of a federal class action would cease 30 days after you opt out.

- If you remain in the class (by not opting out), you may make a claim to all benefits for which you are eligible under the settlement. You would give up any present or future claims against the settling defendants, subject to later opt out rights. You would retain any rights to file lawsuits against non-settling manufacturers and suppliers and against doctors, hospitals, and other health-care providers, subject to applicable statutes of limitation or repose.

TO RECEIVE SETTLEMENT NOTICE, FORMS, AND MORE INFORMATION

To make sure you receive the Settlement Notice (including details concerning the Disease Compensation Program and Disease Compensation Schedule, and the Claim, Registration, and Exclusion Forms) as well as future notices concerning the settlement, complete and return the attached information Request Form, or call the 24-hour Settlement Information Line, 1-800-557-6828 (toll-free U.S.) or 318-609-8600, without delay. Your request will not be a matter of public record and your identity will be protected against disclosure except to the extent

necessary to administer the settlement. The Settlement Notice and Forms will be mailed to you by April 18th (or within 5 days after your request), and in the interest of privacy will show the sender as "MDL 926."

TO MAKE A CLAIM OR REGISTER FOR FUTURE CLAIMS

To make a claim under the Current Disease Compensation Program, you must complete and return a Claim Form, with any necessary supporting documents, postmarked no later than September 16, 1994. To preserve your right to make claims under the Designated Funds or under the Ongoing Disease Compensation Program, you should complete and return a Registration Form, postmarked no later than December 1, 1994.

LATER OPT OUT RIGHTS

Persons who remain in the class will have additional opportunities so opt out at a later date if the projected compensation amounts payable for covered disease under the Disease Compensation Program may be reduced because the available funds are insufficient to pay the full amount of the claims approved under the Program. Should such a reduction occur during processing of Current Disease claims, persons electing at that time to opt out would be entitled to pursue all individual damages claims, including punitive and statutory multiple damages, against the settling defendants. Should such a reduction occur during processing of Ongoing Disease claims, persons electing at that time to opt out would be entitled to pursue individual claims for all damages,

except punitive or statutory multiple damages, against any or all settling defendants. The Settlement Notice describes additional opt out rights afforded to Class Members who are the children of breast implant recipients, with respect to claims of their own personal injury resulting from their mother's breast implants.

TO COMMENT ON OR OBJECT TO THE SETTLEMENT

Class members who do not opt out may comment in support of or in objection to the proposed settlement. To be considered, written comments or objections must be postmarked by June 17, 1994, and mailed to:

MDL 926
P. O. Box 11683
Birmingham, AL 35202-1683

REPRESENTATION BY COUNSEL

You may retain an attorney of your choice. You are not, however, required to have a private lawyer in order to comment on the settlement or make a claim, and Settlement class Counsel designated by the court will automatically represent Class Members who do not have their own lawyers. Class counsel support the settlement and will assist you in the settlement claims process at your request. All fees and expenses of attorneys (whether court-appointed or individually-retained) are subject to court approval and are to be paid from the Designated Fund established for that purpose, rather than from the other Designated Funds or from the Disease Compensation Program. The court has indicated that no more than 25% of the total settlement should be used to pay fees and

expenses of attorneys and the cost of notice and claims administration. Because all legal expenses will be paid from this special Fund, the amount of money you receive will not be affected by whether or not you have a lawyer. The Settlement Notice contains further details concerning attorneys' fees and costs.

THIS NOTICE HAS BEEN APPROVED BY:

Sam C. Pointer, Jr.
United States District Judge

INFORMATION REQUEST FORM
Please send me the Settlement Notice with
Registration, Claim, and Exclusion Forms

Name: _____
Telephone Number: ( ) _____
Address: _____
_____
_____

Type or Print Legibly and Mail To:

MDL 926
P. O. Box 11683
Birmingham, AL 35202-1683

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IN THE FEDERAL DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

CONNIE ALBRECHT, et al., Plaintiff, vs. McGHAN MEDICAL CORP., et al., Defendants.	MOTION FOR CLASS CERTIFICATION OF COUNTS XII, XIII, AND XIV Local Case No. 92-C-0889J MDL Case No. Judge Bruce S. Jenkins

Pursuant to Rule 23(c)(1) and 23(c)(4)(A) Federal Rules of Civil Procedure, plaintiffs respectfully move for an order that Counts XII, XIII, and XIV of this complaint be certified to proceed as a class action.

In support of this motion, plaintiffs rely on the memorandum of law filed herewith.

DATED this 28th day of October , 1992.

ROBERT J. DEBRY &
ASSOCIATES
Attorneys for Plaintiff

By: /s/ Robert J. Debry
ROBERT J. DEBRY

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IN THE FEDERAL DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

CONNIE ALBRECHT, et al., Plaintiff, vs. McGHAN MEDICAL CORP., et al., Defendants.	MEMORANDUM IN SUPPORT OF MOTION FOR CLASS CERTIFICATION RESPECTING COUNTS XII, XIII, AND XIV Local Case No. 92-C-0889J [Related to MDL Docket No. 926] Judge Bruce S. Jenkins

FACTS

Plaintiffs are women who have received silicone gel breast implants. Although asserting three distinctive legal theories, the factual background of this newly filed case is substantially similar with or identical to all other cases which have been consolidated to the Federal District court in Birmingham, Alabama pursuant to MDL Order No. 926.

PROCEDURAL STATEMENT

The case of *Donna Dante v. Dow Corning et al.* has previously been certified to proceed as a nationwide class action. (See Exhibit A.)

For the most part, this case (*Albrecht*) is a carbon copy of the *Dante* case. In fact, Counts I through XI of the *Albrecht* case are virtually word-for-word identical to the Complaint which was certified as a class action in *Dante*.[1] However, Counts I through XI of *Albrecht* are all pleaded as individual claims while those same claims are pleaded as class claims in *Dante*. (Thus, the plaintiffs in *Albrecht* would "opt out" of the *Dante* class action.) Counts XII and XIII of the *Albrecht* Complaint break new ground, and do not appear in any form in the cases consolidated under the MDL umbrella.[2] These Counts are pleaded as a

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[1] After Judge Rubin certified the class in *Dante*, the Complaint was amended to add new theories. It is not clear whether those additional theories are included under the class action umbrella as certified by Judge Rubin.

[2] Count XII is a claim for common law battery. County XIII is a claim asserted under universal humane principles established in the Nuremberg War Code (adopted by the United Nations as international law). Count XIV will not be separately

nationwide class action pursuant to Rule 23(c)(4)(A) F.R.C.P.[3]

POINT I

MOST OF THE REQUIREMENTS FOR CLASS CERTIFICATION HAVE ALREADY BEEN ESTABLISHED

As noted in the Procedural Statement above, a virtually identical class action has already been certified with respect to parallel counts I-XI, in the case of *Donna Dante v. Dow Corning, et al.* (See Exhibit A.) The *Dante* court has already made implicit factual determinations respecting numerosity (Rule 23(a)(1)), commonality (Rule 23(a)(2)), typicality (Rule 23(a)(3)), and superiority (Rule 23(b)(3)).

Under principles of res judicata, or collateral estoppel, or law of the case, it should not be necessary to relitigate these questions in this context.

The doctrine of collateral estoppel is subject to a multi-part test. If this standard is met, it operates to put a particular issue or issues to rest as a matter of law. The test requires: first, "the issue must have been actually litigated" (i.e., contested and submitted for judicial determination); second, "the issue must have been actually

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considered further herein but is based on the Magnusson-Moss Warranty Act. These class action counts are against Dow Corning only.

[3] "When appropriate . . . an action may be brought or maintained as a class action with respect to particular issues." Compare § 30.17 *Manual for Complex Litigation Second.*

and necessarily determined by a court of competent jurisdiction" in a prior trial; third, "preclusion in the second trial must not work an unfairness." *Johns v. Rozet*, 141 F.R.D. 211, 1992 U.S. Dist. LEXIS 1109, 5-6 (D.D.C. 1992) (citing *Jack Faucett Associates, Inc. v. AT&T*, 744 F.2d 118, 125 (D.C. Cir. 1984), cert. denied 469 U.S. 1185). *See also, Cotton States Mutual Ins. Co. v. Anderson*, 749 F.2d 663, 666 (11th Cir. 1984) (quoting *Williams v. Bennett*, 689 F.2d 1370, 1381 (11th Cir. 1982) (listing the three elements of the collateral estoppel test). Other courts break down the elements of collateral estoppel into four parts:

> (1) the issue sought to be precluded must be the same as that involved in the prior action; (2) the issue must have been actually litigated to final judgment; (3) the determination must have been essential to the final judgment; and (4) the party against whom estoppel is invoked must have been fully represented in the prior action.

In re Tom Livaditis, 122 Bankr. 330, 334 (Bankr. N.D. Ill. 1990) (citing *Klingman v. Levinson*, 831 F.2d 1292, 1295 (7th Cir. 1987)). The tests are identical in substance. Collateral estoppel will thus not apply if the three or four pronged test is not satisfied, such as situations where a district court's ruling is "avowedly tentative." *See In re Tom Livaditis, supra* at 335 (citing cases applying this exception).

Class certification has, itself, been expressly considered as an issue subject to collateral estoppel in several cases. In *Johns v. Rozet, supra*, the court agreed with the plaintiffs that the "Superior Court's previous class certification bars relitigation of the issue [of class certification] under the doctrine of issue preclusion." In *In re Tom Livaditis, supra*, the bankruptcy court ruled that the prior

order of the district court ordering class certification must be given preclusive effect in a subsequent action since the elements of collateral estoppel were satisfied. In *Lee v. Williamson*, 659 F.Supp. 813, 821 (S.D. Ga. 1987), the court observed, quoting *McLaughlin v. Bradley*, 602 F.Supp. 1412, 1417 (D.D.C. 1985): "Sanctions are especially appropriate in situations were [sic] the doctrines of res judicata and collateral estoppel plainly preclude relitigation of the suit." also cited was *Robinson v. National Cash Register Co.*, 808 F.2d 1119 (5th Cir. 1987).

Collateral estoppel essentially hinges on whether the same issue of "ultimate fact" was previously litigated, and is, primarily, a factual question. The issue may pertain to mixed questions of law or fact, or even to "pure questions of law if the claims stem from the same transaction or if injustice will otherwise result." *Romano v. Kimmelman*, 464 A.2d 1170, 1175 (N.J. Super. Ct. App. Div. 1983). *See also Bastian v. Petren Resources Corp.*, 681 F.Supp. 530, 535 (N.D. Ill. 1988) ("The fact that the [prior] decision [denying certification] was based on nearly identical questions of fact and law, and was affirmed by the Third Circuit, mandates that this court give it deference here." (Citing *Premier Elec. Const. Co. v. NERC*, 814 F.2d 358, 367 (7th Cir. 1987); *Colby v. J.C. Penney Co.*, 811 F.2d 1119, 1123-24 (7th Cir. 1987).

In summary, it is not necessary to relitigate the factual basis for class certification since the essential facts have already been litigated in the *Dante* case.

POINT II

THE REQUIREMENTS OF RULE 23(a) (4) (ADEQUATE REPRESENTATION) ARE MET

In order to certify a class action, a court must determine that, "the representative parties will fairly and adequately protect the interests of class members." Rule 23(a)(4). Courts look primarily to the qualifications of class counsel – not to the named plaintiffs – to determine whether the class will be adequately protected under Rule 23(a)(4):

> The single most important factor considered by the courts in determining the quality of the representatives ability and willingness to advocate the cause of the class has been the caliber of the plaintiff's attorney.

The Class Representative: The Problem of the Absent Plaintiffs, 68 NW UL Rev. 1133, 1136 (1974); *see also, Newberg on Class Actions* at § 3.24.

Notwithstanding the effects of collateral estoppel in other respects (Point I above), it is necessary to consider Rule 23(a)(4) because a different team of attorneys is proposed to manage Counts XII, XIII and XIV of the *Albrecht* class action.

The qualifications of the *Albrecht* class counsel may be summarized as follows:

> Robert J. DeBry will serve as lead trial counsel. Robert J. DeBry has been awarded a certificate of special competence in Civil Trial Advocacy by the National Board of Trial Advocacy. He is especially experienced in litigating silicone issues. *See, Celia Anderson v. The American Society of Plastic & Reconstructive Surgeons*, 807 P.2d 825

(Utah 1990) and *Anderson v. Department of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). Mr. DeBry is also experienced in class litigation. *See, e.g., Madsen v. Prudential Federal Savings & Loan Assoc.*, 635 F.2d 797 (10th Cir. 1981).

Samuel D. Thurman is now of Counsel to the firm of Robert J. DeBry & Associates. Mr. Thurman is a nationally known expert on torts and has served as an advisor on the Restatement (Second) of Torts for many years. For over a decade, Mr. Thurman was Dean of the University of Utah Law School. Mr. Thurman is listed in "Who's Who" and "Who's Who in American Law." He has authored many nationally recognized textbooks.

Wallace R. Bennett is Of Counsel to the firm of Robert J. DeBry & Associates. Mr. Bennett is Professor of Law Emeritus and was Associate Dean of the University of Utah College of Law. Mr. Bennett is former Commissioner on Uniform Laws, and has experience with current multistate class litigation. He holds an L.L.M. degree from Harvard University School of Law and an L.L.M. degree from New York University School of Law.

Frank E. Moss is Of Counsel to the firm of Haley & Stolebarger. Mr. Moss is a former prosecuting attorney and was the ranking United States Senator who co-authored the Magnuson-Moss Consumer Products Warranty Act, 15 U.S.C. § 2301 *et seq.*

D. Frank Wilkins is Of Counsel to the firm of Berman and O'Rorke. Mr. Wilkins is a former trial court judge and a former Justice of the Utah Supreme Court.

David D. Bennett holds an Honors Chemistry degree from the University of Utah and a Masters degree from the Department of Cellular, Viral and Molecular Biology at the Medical School of the University of Utah. He has published in scientific journals and practices law, consulting with law firms in science-related matters.

Karen M. Thomas is a Registered Nurse in addition to being a licensed attorney. She holds both an associate degree and a Bachelor of Science Degree in nursing. She possesses a varied health care background having worked as an operating room nurse for a plastic surgeon who performed breast surgery before attending law school, to serving as in house counsel for two different hospital corporations before entering private law practice.

See Complaint at paragraph 73.

POINT III

CONSIDERATIONS OF POLICY AND JUDICIAL ECONOMY SUPPORT CERTIFICATION OF THIS SEPARATE CLASS

There are a number of policy considerations which support expedited certification of the *Albrecht* sub-class for Counts XII and XIII.[4] These are:

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[4] These same policy considerations are also relevant under the rubric commonly referred to as "superiority" under Rule 23(b)(3). However, as described below, this case can be certified without reference to Rule 23(b)(3).

A. Early Trial

The continuing battery claim (Count XII) and the claim based on the Nuremberg Code (Count XIII) are ready for immediate trial. Plaintiffs' counsel do not require a pre-trial discovery beyond the evidence and data already available in the public domain. Dow Corning may wish to depose plaintiffs' experts, but that could be accomplished in a matter of weeks. (Indeed, Dow Corning has already deposed these very experts in several different cases.)

B. Simplification of Issues – Causation

Far and away the most difficult tort issue in breast implant cases is customarily "causation." That is, did the silicone gel *cause* the injury. (viz. scleroderma, systemic lupus erythematosus, rheumatic diseases, human adjuvant disease, etc.) Plaintiffs have won some of these cases, but have also lost other cases on causation grounds. (See Exhibit B.) Most cases under the MDL umbrella will require extensive pre-trial discovery relating to causation. However, causation is simply not an issue in the claims for a continuing battery (Count XII) and unlawful human experimentation (Count XIII) of the *Albrecht* case.

C. Simplification of Issues – Battery[5]

Count XII pleads a claim for common law battery. The generic simplicity of this ancient tort has important relevance to this case. The unadorned requirement to establish battery is merely an offensive contact. See generally, *Restatement (Second) of Torts* §§ 13-20.

In order to establish battery, plaintiffs need not show any particular causation or injury. Section 15 of the Restatement gives the following example of a battery:

> A has a wart on his neck. His physician, B, advises him to submit to an operation for its removal. A refuses to do so. Later A consents to another operation, and for that purpose is anesthetized. B removes the wart. The removal in no way affects A's health, and is in fact beneficial. A has suffered bodily harm.

The *Albrecht* Complaint alleges that Dow Corning had knowledge of certain dangers and defects in the silicone gel breast implant; and that, Dow Corning failed to disclose such defects. Therefore plaintiffs assert that any consent given by women for the implants was vitiated by reason of material nondisclosures and misleading representations. Section 892B of the Restatement (Second) of Torts gives the following example of a failure to disclose material facts:

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[5] This line of reasoning is not intended to prove that a multiple party battery has in fact occurred. That must wait for trial. However, this section will demonstrate that the theory of common law battery is ideally suited to breast implant litigation; and for the vast majority of women, battery would be a theory of choice.

> A gives B a vile tasting medicine to drink. A knows that the medicine is poisonous and that B does not know it. A is subject to liability to B for battery.

Since the breast implant is still in the body of most plaintiffs, the battery continues. Because the battery continues to this day, no statute of limitations forecloses the claim. *See e.g., Parker v. Vaughn,* 183 S.E. 2d 605 (GA. App. 1971).

The basic measure of damages is simply the cost of ending the battery (i.e., removing the breast implant). There may also be other damages; however, the basic cost of removing the implant will set baseline damages for all plaintiffs.

D. Simplification of Issues – Nuremberg Code[6]

Basic ethical standards for all human experimentation were declared in the Nuremberg War trials. In those momentous cases, Nazi doctors were accused of various atrocities. The doctors' defense was that they were simply conducting experiments that could be beneficial for mankind. The tribunal declared that all mankind should be

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[6] The purpose of this section is not to prove that violations of the Nuremberg Code have occurred. That must wait for trial. However, this section will demonstrate that the Nuremberg Code is an appropriate legal theory and standard for breast implant cases. Every woman who has received a silicone gel breast implant was insufficiently informed and therefore, as a practical matter, became an unwilling participant in what has become a human experiment of staggering scale.

subject to limitations when individuals are used for experimentation.

By these precepts, sixteen of twenty-three defendants were found guilty of crimes against humanity. See, *United States v. Karl Brandt, Trials of War Criminals Before the Nuremberg War Tribunal* Vol. I & II, The Medical Case. Washington D.C.: U.S. Government Printing Office (1948).

The United Nations General Assembly unanimously adopted a resolution on December 11, 1946 affirming the "principles of international law recognized by the charter of the Nuremberg tribunal and the judgment of the tribunal." It has been said to be an "inescapable conclusion that the code is part of international law. . . . " Annas, *The Law of Informed Consent to Human Experimentation: Preliminary Report Prepared for the National Committee for the Protection of Human Subjects of Biomedical Research.*

The Nuremberg Code can properly be regarded as a basic ethical standard for all human experimentation, and has been used by other courts as a standard of care in the field of human experimentation. *See e.g.*, Curran, *Legal Codes in Scientific Research Involving Human Subjects*, 3 LEX ET SCIENTA 65 (1966); *Whitlock v. Duke University*, 637 F. Supp. 1463, 1470 (M.D. N.C. 1986); *Kaimowitz v. Department of Mental health for the State of Michigan*, Mental Disability L. Rep. 147 (Mich. Cir. Ct. 1983).

In the case of *United States v. Stanley*, 483 U.S. 669 (1987) a discharged serviceman sued his former superiors for causing LSD to be administered to him without his knowledge or consent during Army experimental tests. The majority opinion held that because of his military status at the time he was given LSD, Stanley could not

sue. In a scathing dissent, Justice Brennen complained that the court should not apply precedent which prevented a soldier from suing superior officers for constitutional violations. According to Justice Brennen there should be no immunity for violation of the tenets of the Nuremberg Code. Justice Brennen stated that the Code applies to "all citizens." 483 U.S. at 687. Justice O'Connor in her dissent stated that in her opinion, the constitutional guarantee of due process of law guarantees the right to seek redress for a violation of the principles of the Code of Nuremberg. 483 U.S. at 710. It seems tolerably clear that the Nuremberg Code would certainly apply in non-military cases.

The Nuremberg Code explicitly provides that:

> The voluntary consent of the human subject is essential. This means that the person involved . . . should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

* * *

> The experiment should be so designed and based upon the results of animal experimentation . . . that the anticipated results will justify the performance of the experiment.

Nuremberg Code at paragraphs 1 and 3.[7]

Plaintiffs' Complaint emphatically alleges that adequate animal tests were not conducted; and that Dow Corning did not reveal all of the known risks and side effects to women who received the breast implants. In effect, the approximate 1,000,000 women who received breast implants became, without their knowledge or real consent, subjects of mass human experimentation. (See Exhibit D.)

Finally, the Code itself indicates an appropriate remedy:

> During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he [or she] has reached the physical or mental state where continuation of the experiment seems to him [or her] to be impossible.

Nuremberg Code at paragraph 9.

Under this universal concept, a mandatory affirmative injunction should issue requiring Dow Corning to inform all recipients of Dow Corning breast implants of the known risks and side effects. After being fully informed, each woman should have an opportunity, at her election, to bring the experiment to an end by having the implants removed at Dow Corning's expense.

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[7] The entire Nuremberg Code is attached at Exhibit C.

E. Prevention

The existing class action (*Dante*) is well suited to compensate women who have been physically injured through use of a breast implant. However, the *Dante* class action does little to assist women who can not yet show that they have sustained demonstrable injury.

The continuing battery and the Nuremberg Code concepts provide compensable bases for past injuries *and* are remedial vehicles for preventing future injuries. The battery and the Nuremberg Code theories provide grounds for removal of breast implants *before* further injury occurs. This judicially declared redress would be in the nature of a nationwide recall.

Since the beginning of time, the law has valued prevention of injury over mere payment for past injury. Thus, an ancient Latin maxim reads: *Praestat cautela guam medela* ("Causation or prevention is better than cure"). Another maxim is of like kind: *Le salut du peuple est la supreme loi* ("The safety of the people is the supreme law."). Mr. Justice Cardozo stated: "The final cause of law is the welfare of the society. The rule that misses its aim cannot permanently justify its existence." *The Nature of Judicial Process,* 66 (1921). In the case of *NLRB v. Robbins,* 437 U.S. at 239-40, the court instructed: "[The] possibility of deference arising from post hoc disciplinary action is no substitute for a prophylactic rule that prevents the harm. . . . "

F. Limited Funds and the 23(b)(1)(B) Class

The *Dante* case was certified under Rule 23(b)(3). The *Albrecht* case also qualifies for 23(b)(3) treatment. However, in addition, *Albrecht* also meets the requirements of Rule 23(b)(1)(B).[8]

Rule 23(b)(1)(B) is especially suited to limited fund cases. See *Newberg on Class Actions*, § 4.09. The *Dante* class action raises the distinct *possibility* of a limited fund case.[9] The *Albrecht* class action makes it a virtual certainty that Dow Corning's fund of corporate assets and insurance will not be adequate to the totality of the compensable claims presented.

G. Injunctive Relief and the 23(b)(2) Class

The Court may fashion relief, in part, in the form of a mandatory injunction that Dow Corning end the continuing battery and unlawful human experimentation. Such injunctive relief would support certification under Rule 23(b)(2). See *Newberg on Class Actions*, § 4.11.

H. Notice

If the *Albrecht* case is certified under Rule 23(b)(1)(B) or under 23(b)(2), no notice is necessary. *Newberg on Class Actions*, § 8.05.

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[8] Class actions that qualify for class certification under 23(b)(1)(B) should not normally be certified under 23(b)(3). See *Newberg on Class Actions*, § 4.20

[9] Some fact finding is necessary to prove the limited fund. *In re Bendectin Products Liability Litigation*, 749 F.2d 300 (6th Cir. 1984).

Nevertheless, since a notice has already been sent out in the *Dante* case, the court may yet have an occasion to order that an amended notice be sent. In any amended notice, it would be easy to disclose the alternative concepts of the *Albrecht* (b)(1)(B) and (b)(2) classes.

CONCLUSION

In addition to the existing (*Dante*) class actions, this court should expeditiously certify at least two additional causes of action: battery and claims based on Nuremberg Code. Certification of these additional claims would give the vast majority of women with breast implants an opportunity to have those implants removed before a disease process begins or continues detrimentally.

DATED this 25th day of October, 1992.

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May 11, 1993

Honorable Sam C. Pointer
U.S. District Court
Northern District of Alabama
U.S. Courthouse
Birmingham, AL 35203

Dear Judge Pointer:

We have received a copy of a letter from Dow Corning's attorney (Dr. Frank Woodside) in response to our "Urgent Request to Set Hearing Date in the case of *Albrecht v. McGhan Medical, et al.* (92-P-11104-S)." Dr. Woodside's letter references a hearing of January 22, 1993,

when the Court apparently made a bench ruling regarding the *Albrecht* case.

We must apologize to the Court that we were not in attendance at that hearing to respond to questions or otherwise assist the Court. For whatever reason, we were simply not aware (until receipt of Dr. Woodside's letter) that this matter would be called on the January 22 calendar.

However, based upon Dr. Woodside's letter, we are now aware of the Court's concern as expressed in that January 22 hearing:

> To the extent that these are appropriate claims and to the extent were [sic] going to have a class, *I can deal with it in other litigation* without the need to utilize this particular device for certain limited theories of action. (Emphasis added.) (January 22, 1993 Transcript at p. 161-162.)

If we had been present, we would have responded that the Court is absolutely correct as a *theoretical* matter. However, as a *practical* matter serious problems arise if class certification in *Albrecht* is delayed. We would have further observed that the practical problems of such delay would be especially serious in the context of settlement discussions. Thus, we would have argued as follows:

First, a partial settlement (not including the *Albrecht* claims) may deplete available assets and insurance coverage. Therefore, any later judgment in *Albrecht* may be largely meaningless.[1]

Second, a partial settlement (not including the *Albrecht* claims) would require the Court to send confusing notice of such partial settlement to class members. Further, class members, being unaware of their rights under common law battery and Nuremberg Code theories, would be confused about whether or not to opt out of the class.

Third, neither the Lead Counsel's Committee in *Dante* nor the Plaintiffs' Steering Committee in the *MDL* case can properly evaluate or negotiate claims (for battery and Nuremberg Code violations) which they have never even thought of.

Fourth, the existing *Dante* attorneys and the existing *MDL* Plaintiffs' Steering Committee seem to be doing an adequate job to protect the interests of those women with a bodily injury. However, a legitimate question might be raised whether the *Dante* and *MDL* attorneys have sufficiently protected the uninjured women. Certainly the

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[1] Assume conservatively 500,000 women in the *Albrecht* class. These would be women who have suffered no bodily injury; but who are, nonetheless, entitled to monetary damages to end the continuing battery or to end the unlawful experiment. Assume conservatively a $10,000 judgment or settlement for each of the 500,000 class members in *Albrecht*. That would yield a total judgment of *five billion dollars*! If Dow Corning still has five billion dollars left after settling *Dante*, there is no problem.

Dante and *MDL* attorneys have not even pleaded appropriate theories of relief for uninjured women. [viz. common law battery and violations of the Nuremberg Code.] Thus, the *Albrecht* complaint might be viewed as an appropriate vehicle through which uninjured women may receive proper representation as they compete against injured women for a fair allocation of the limited funds.

Again, we apologize that we were not present at the January 22 hearing; however, these additional comments (above) may assist the Court in assessing the need for a further hearing on class certification in *Albrecht*.

Sincerely,

/s/ Robert J. Debry
ROBERT J. DEBRY

RJD/vah
cc: Plaintiffs' Liaison Counsel
Defendants' Liaison Counsel